Reframing ‘Hard to Reach’: Culturally Adapted Therapy and Engagement in Maternal Mental Health Research with South Asian Communities

by

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RESEARCH STUDENT DECLARATION FORM

Type of Award	**PhD by published works**
School	**School of Nursing and Midwifery**

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ABSTRACT

Background

This thesis presents and critically evaluates a coherent programme of research conducted over thirteen years, centred on improving perinatal mental health care for British South Asian (BSA) women. The work describes a culturally humble, community-centred approach to research recruitment, intervention design, delivery, and evaluation.

Research Context and Development

The programme began with qualitative work exploring how BSA women express distress and navigate stigma, silence, and family dynamics. These insights informed the development and refinement of culturally adapted psychological interventions across the ROSHNI[1] trials. Learning travelled bidirectionally between the UK and Pakistan, where task-sharing models and culturally grounded communication shaped UK practice. This global partnership also shaped my development from research assistant to research leader.

Methods and Outputs

The thesis draws on mixed-methods feasibility studies, nested qualitative analyses, intervention adaptation processes, training and governance frameworks, and a large randomised controlled trial with an embedded economic evaluation. Across these trials, I contributed to management and embedded a cultural humility lens within recruitment and retention of participants, intervention refinement, research governance, facilitator training, patient and public involvement and engagement.

Key Contributions

The research demonstrates that culturally adapted interventions for postnatal depression are clinically effective, economically sound, and acceptable to women who have historically been underserved by mainstream services. A central conceptual contribution is the articulation of cultural humility as a methodology that moves beyond cultural competence, emphasising reflexivity, shared decision-

[1] The word ROSHNI means light in Urdu/Hindi.

making, and attention to power. The thesis reframes community engagement as a matter of epistemic justice, challenging labels such as “hard to reach”.

Impact and Future Directions

The programme has influenced policy, practice, and national research infrastructures. Its findings have contributed to global discussions on equity in perinatal mental health and shaped my leadership role in research. Future work will focus on embedding these insights within wider NIHR research infrastructures and contributing to national policy and programme development through my roles as co-applicant on emerging research trials.[2]

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[2] https://www.fundingawards.nihr.ac.uk/award/NIHR209260, https://www.LSCFT.nhs.uk/news/lancashire-and-south-cumbria-host-new-gbp11m-mental-health-research-group

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GLOSSARY OF TERMS AND ABBREVIATIONS

Terms

Behavioural Activation - A therapeutic technique used in Cognitive Behaviour Therapy (CBT) that focuses on increasing engagement in meaningful activities to improve mood and reduce depressive symptoms.

British South Asian (BSA) - Refers to individuals in the UK with heritage from South Asian countries including Pakistan, India, Bangladesh, Sri Lanka, and Nepal.

Cognitive Behavioural Therapy (CBT) - A structured, evidence-based psychological therapy that helps individuals identify and modify unhelpful thoughts and behaviours.

Collectivist Cultures - Cultures in which identity, decision-making, and wellbeing are shaped by family and community relationships rather than individual autonomy.

Community-Centred Research – Research approaches that prioritise partnership with communities, shared ownership, and responsiveness to cultural and social contexts.

CEI (Community Engagement and Involvement) - An approach that ensures communities are actively involved in shaping research design, delivery, and decision-making. CEI emphasises partnership, shared ownership, and responsiveness to cultural and social contexts.

Cultural Adaptation - The process of modifying interventions, materials, and research procedures to align with the cultural, linguistic, and social contexts of specific communities.

Cultural Competence – An approach focused on acquiring knowledge about cultural groups. It implies mastery of culture, in contrast to cultural humility, which emphasises reflexivity and partnership.

Cultural Humility - A lifelong, reflective practice that emphasises openness, power sharing, and partnership with communities. It contrasts with cultural competence by focusing on relational accountability rather than mastery of cultural knowledge.

Cultural Safety - A framework originating in Māori nursing scholarship that emphasises environments in which service users feel respected, heard, and free from discrimination.

Cultural Validity – The extent to which assessment tools, interventions, or research processes accurately reflect and respect the cultural context, language, and lived experiences of the target population.

Epistemic Justice - A concept describing fairness in whose knowledge is valued. In this thesis, it refers to recognising BSA women as experts in their own experiences and co-constructors of knowledge.

Extended Family Systems- Family structures common in South Asian communities where multiple generations live together or maintain close involvement in daily decision-making.

Izzat - A cultural concept referring to family honour, reputation, and social standing. It strongly shapes help-seeking behaviours and emotional expression in many South Asian communities.

Idioms of Distress - Culturally specific ways of expressing emotional suffering, often through metaphors, somatic symptoms, or relational language.Learning Through Play Plus (LTP Plus) – An integrated maternal mental health and early child development intervention tested in Pakistan, informing global learning within the ROSHNI trials.

Maternal Mental Health - The emotional and psychological wellbeing of women during pregnancy and the postnatal period, including conditions such as postnatal depression, anxiety, and trauma.

Narrative Humility - An approach that emphasises listening to individuals' stories without assuming full understanding, acknowledging the limits of one's interpretive frameworks.

Perinatal Period - The time from conception to one year after birth.

Perinatal Mental Health (PMH) – The emotional and psychological wellbeing of women during pregnancy and up to one year after birth, including conditions such as depression, anxiety, and trauma.

Positive Health Programme (PHP) – A culturally adapted, low-intensity CBT-based group intervention for postnatal depression delivered in the ROSHNI trials.

Postnatal Depression (PND) - A depressive disorder occurring after childbirth, characterised by low mood, fatigue, anxiety, and difficulties bonding with the baby.

Quality-Adjusted Life Years (QALYs) - A standard measure used in health economics to assess the value of health interventions by combining length of life with quality of life. One QALY represents one year of life in perfect health.

Relational Ethics - An ethical approach that emphasises trust, reciprocity, and the quality of relationships in research and clinical practice.

Reverse Innovation - The process by which learning from low- and middle-income countries (LMICs) informs and improves practice in high-income settings.

ROSHNI – An Urdu/Hindi term meaning *light*. The name was chosen by individuals with lived experience for the ROSHNI-D and ROSHNI-2 trials to reflect the programme's aim of bringing visibility and culturally meaningful support to British South Asian women. It is not an acronym.Somatic Expression - The communication of emotional distress through physical symptoms such as headaches, fatigue, or bodily pain.

Task-sharing - A global mental health strategy in which nonspecialist workers are trained to deliver psychological interventions, increasing access in low-resource settings.

Thinking Healthy Programme (THP) – A World Health Organisation-endorsed CBT-based intervention for perinatal depression developed in Pakistan, forming part of the theoretical foundation for the ROSHNI trials.

Abbreviations

BAME	Black, Asian and Minority Ethnic (now used cautiously due to limitations)
BSA	British South Asian
CBT	Cognitive Behavioural Therapy
CEI	Community Engagement and Involvement
CI	Chief Investigator
GCP	Good Clinical Practice
GMH	Global Mental Health
GP	General Practitioner
HEI	Higher Education Institution
HTA	Health Technology Assessment
ICH	International Council for Harmonisation
LMIC	Low- and Middle-Income Countries
LSCFT	Lancashire and South Cumbria NHS Foundation Trust
LTP Plus	Learning Through Play Plus
MMH	Maternal Mental Health
MRC	Medical Research Council
NHS	National Health Service
NIHR	National Institute for Health and Care Research

PILL	Pakistan Institute of Living and Learning
PPIE	Patient and Public Involvement and Engagement
PHP	Positive Health Programme
PMH	Perinatal Mental Health
PND	Postnatal Depression
QALY	Quality-Adjusted Life Year
RA	Research Assistant
RCT	Randomised Controlled Trial
ROSHNI-D	ROSHNI Depression trial (Exploratory RCT)
ROSHNI-2	Multicentre RCT of the Positive Health Programme
THP	Thinking Healthy Programme
WHO	World Health Organisation

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FARAH LUNAT: Published Works Included in the Thesis

Short citations used throughout the thesis as indicated in *green bold and italics.*

1. **Khan, S., Lovell, K., Lunat, F., Masood, Y., Shah, S., Tomenson, B., & Husain, N. (2019).** Culturally adapted cognitive behavioural therapy-based intervention for maternal depression: A mixed-methods feasibility study. *BMC Women's Health, 19*(1), 21. ***(Khan et al, 2019)***
2. **Husain, N., Lunat, F., Lovell, K., Sharma, D., Zaidi, N., Bokhari, A., Syed, A., Tomenson, B., Islam, A., Chaudhry, N., & Waheed, W. (2023).** Exploratory RCT of a group psychological intervention for postnatal depression in British mothers of South Asian origin: ROSHNI-D. *Acta Psychologica, 238,* 103974. ***(Husain, Lunat et al, 2023)***
3. **Masood, Y., Lovell, K., Lunat, F., Atif, N., Waheed, W., Rahman, A., Mossabir, R., Chaudhry, N., & Husain, N. (2015).** Group psychological intervention for postnatal depression: A nested qualitative study with British South Asian women. *BMC Women's Health, 15*(1), 109. ***(Masood et al, 2015)***
4. **Husain, N., Zulqernain, F., Carter, L. A., Chaudhry, I. B., Fatima, B., Kiran, T., Chaudhry, N., Naeem, S., Jafri, F., Lunat, F., Haq, S. U., Husain, M., Roberts, C., Naeem, F., & Rahman, A. (2017).** Treatment of maternal depression in urban slums of Karachi, Pakistan: A randomized controlled trial (RCT) of an integrated maternal psychological and early child development intervention. *Asian Journal of Psychiatry, 29,* 63-70. ***(Husain et al, 2017)***
5. **Husain, N., Chaudhry, N., Furber, C., Fayyaz, H., Kiran, T., Lunat, F., Rahman, R. U., Farhan, S., & Fatima, B. (2017).** Group psychological intervention for maternal depression: A nested qualitative study from Karachi, Pakistan. *World Journal of Psychiatry, 7*(2), 98. ***(Husain et al, 2017)***
6. **Husain, N., Lovell, K., Chew-Graham, C., Lunat, F., McPhillips, R., Atif, N., ... & Morriss, R. (2022).** Multicentre randomized controlled trial of a group psychological intervention for postnatal depression in British mothers of South Asian origin (ROSHNI-2): Study protocol. *BJPsych Open, 8*(1) ***(Husain et al, 2022)***
7. **Lunat, F., Islam, A., Ahmed, F., Begum, J., Aseem, S., Lorgat, M., Bhatti, H., Masood, T., Zaidi, N., & Husain, N. (2020).** ROSHNI-2: Using a culturally adapted model of recruitment, engagement and retention to mental health research for British South Asian women experiencing symptoms of postnatal depression. *International Society for the Study of Behavioural Development, 2020 Bulletin, 1,* serial 77. ***(Lunat et al, 2020)***
8. **Husain, N*., Lunat, F*., Lovell, K., Miah, J., Chew-Graham, C. A., Bee, P., Waqas, A., Pierce, M., Sharma, D., Atif, N., & Aseem, S. (2024).** Efficacy of a culturally adapted, cognitive behavioural therapy-based intervention for postnatal depression in British South Asian women (ROSHNI-2): A multicentre, randomized controlled trial. *The Lancet, 404*(10461), 1430-1443 *joint first authors. ***(Husain, Lunat et al 2024)***
9. **Husain, N., Lovell, K., Chew-Graham, C. A., Lunat, F*., Bee, P., Pierce, M., ... & Morriss, R. (2025).** A group psychological intervention for postnatal depression in British mothers of South Asian origin-the ROSHNI-2 RCT. *Health Technology Assessment (Winchester, England)*, *29*(6), 1. *Corresponding author ***(Husain, Lovell et al, 2025)***
10. **Ullah, A., Lunat, F*., Brugha, T., Pierce, M., Morriss, R., Sharma, D., ... & Husain, N. (2025).** Cost-effectiveness of a group psychological intervention for postnatal depression in British south Asian women: an economic evaluation from the ROSHNI-2 trial. *The Lancet Psychiatry*. ***(Ullah, Lunat et al, 2025)***

CHAPTER 1: INTRODUCTION

1.1 Introducing the topic and core concepts

British South Asian (BSA) women experience some of the highest rates of perinatal mental health (PMH) difficulties in the UK,yet remain consistently underrepresented in research and underserved by clinical services (Jankovic et al, 2020). Structural inequities, stigma, language barriers, and diagnostic mismatch contribute to poorer access, delayed help-seeking, and unmet need (Jovanovic et al, 2025; ***Masood et al., 2015; Khan et al., 2019; Husain, Lunat et al., 2024***). My work aimed to address these disparities through research approaches grounded in cultural humility. Cultural humility is the central lens in this thesis, through which I examine inequities in maternal mental health (MMH) care and provide the conceptual foundation for the model of adaptation developed across the ten co-authored, peer-reviewed publications presented in this thesis. Unlike cultural competence, which implies mastery of cultural knowledge, cultural humility emphasises reflexivity, power sharing and lifelong learning. It recognises that communities are experts in their own lives and that research must be developed *with* communities, not *to* them. Originally conceptualised by Tervalon and Murray-García (1998) as a commitment to self-reflection, power awareness, and respectful partnership, cultural humility has since been applied across mental health settings to strengthen therapeutic alliances with diverse populations (Mosher et al., 2017. This concept is described in more detail in Chapter 2.

The cultural humility model described in this thesis is grounded in evidence from ROSHNI-D[3] ***(Masood et al, 2015; Husain, Lunat et al, 2023)*** and ROSHNI-2 ***(Husain, Lunat et al 2024; Husain, Lovell et al 2025)***, two National Institute for Health and Care Research (NIHR)-funded randomised controlled trials (referred to here collectively as the ROSHNI trials). These trials evaluate the Positive Health Programme (PHP), a culturally adapted, low-intensity Cognitive Behaviour Therapy (CBT)-based intervention for postnatal depression (PND) in BSA communities. Delivered in group settings by trained facilitators, PHP integrates behavioural activation, problem solving, and culturally meaningful metaphors to support women experiencing postnatal depression. The intervention is described in Chapter 3, with an overview of the sessions provided in Appendix B. Across the two ROSHNI trials, I

[3] The word ROSHNI means light in Urdu/Hindi

applied cultural humility not only as a methodological stance, but as a whole system approach to research design, governance, and delivery. This included shaping recruitment pathways, adapting assessment procedures, developing bilingual facilitator training, and embedding culturally grounded decision-making within trial operations. These practices ensured that interventions and research procedures were responsive to the languages, metaphors, and lived realities of BSA women. The work documented in the included publications shows how culturally humble, community-centred approaches enabled the engagement of more than 4,000 BSA women in one of the largest MMH trials of its kind. More importantly, these approaches demonstrate methodological originality. This moves the contribution beyond community engagement and positions cultural humility as a transferable research methodology capable of strengthening equity across diverse research infrastructures. Culturally adapted, community- engaged approaches can overcome longstanding barriers to participation, challenging the narrative that BSA communities are "hard to reach". Instead, the findings show that when research is designed with communities and delivered with cultural humility, engagement becomes not only possible but sustained. This is explored in further detail in Chapter 3.

The ROSHNI trials were built on the back of a wider global mental health partnership between the UK and Pakistan, drawing on evidence from trials in Pakistan that tested the Thinking Healthy Programme (THP) and Learning Through Play Plus (LTP Plus) intervention (***Husain et al., 2017***; Rahman et al., 2008). THP is a World Health Organisation (WHO)-endorsed, CBT-based intervention to treat perinatal depression. It demonstrated strong clinical effectiveness in Pakistan and provided the theoretical and methodological foundation for culturally adapted CBT approaches later used in the two ROSHNI trials. LTP Plus integrates early child development strategies with MMH support, showing significant improvements in both maternal wellbeing and children's cognitive, language and social outcomes. This global–local collaboration added to my understanding of the concept of cultural humility and cultural adaptations used in the UK, and later informed reverse innovation back to Low- and Middle-Income Countries (LMICs). This bidirectional learning is explored in more detail in Chapter 4 and Appendix A includes a case study prepared for the NIHR that describes this in more detail.

1.2 Introducing the researcher

My commitment to maternal mental health is deeply personal. During my adolescent years, I watched my mother navigate pregnancy, postpartum, and neonatal loss with limited support. Although she had lived in the UK since the age of 15, she lacked the confidence to advocate for herself, and the services available at the time were not designed with women like her in mind. Even if services had been offered, it is unlikely they would have provided what our family needed. These experiences shaped my understanding of the gaps in care and cemented my dedication to improving MMH for women whose needs are often overlooked. Throughout my career, I have spoken with hundreds of research participants; it is their collective experiences that have moulded both my research interests and my approach to cultural humility. My first participant home visit in 2012 was with a BSA mother who had survived severe domestic abuse and was raising her child alone in a women's shelter. That encounter changed me. It revealed the gravity of the challenges faced by many women, and their extraordinary resilience continues to inform my research lens. Since then, I have heard many more stories, some hopeful, some harrowing, and each has reinforced the need for research that listens, adapts, and centres their lived experiences.

The ten publications (full copies included in Appendix D) detailed in this thesis chart my progression from Research Assistant (RA) to research leader and document my sustained contributions to evidence generation, trial delivery, and community engagement from 2012 to 2026. Alongside these, I also draw on additional co-authored publications that, while not included in the formal list of publications for the thesis, further illustrate the development of my methodological and conceptual thinking. After completing my master's degree at the University of Lancashire[4] in 2012, I began my career as an RA on ROSHNI-D.

Between 2012 and 2016, I strengthened my skills in research, contributed to the dissemination of ROSHNI-D findings, and worked closely with Professor Nusrat Husain (Chief Investigator (CI) on ROSHNI trials) to develop the successful NIHR Health Technology Assessment (HTA) application for ROSHNI-2, a multi-centre clinical and cost-effectiveness trial. When the trial was funded in 2016, I became Deputy Trial Manager (I progressed to Trial Manager in 2020), and from 2016 to 2020

[4] Formerly University of Central Lancashire (UCLAN)

I led the delivery and operational management of ROSHNI-2. As trial manager and researcher, I was responsible for recruitment of staff, study set-up, liaising with NHS sites (primary and secondary care), recruitment and retention of participants, intervention delivery, training and supervising researchers, and coordinating trial operations across multiple sites (Northwest, Midlands, Yorkshire, London and Glasgow[5]).

From 2020–2025 I worked on dissemination, impact, and academic outputs from the ROSHNI-2 trial, alongside my day-to-day role as Research Operations Manager at Lancashire and South Cumbria NHS Foundation Trust (LSCFT).

This thesis reflects my learning and outputs from NIHR and Medical Research Council (MRC)-funded trials conducted at leading institutions including LSCFT, Pakistan Institute of Living and Learning (PILL), and the University of Manchester. It also draws on strong partnerships with Higher Education Institutions across the UK and with voluntary, community, faith, and social enterprise organisations. This transdisciplinary and transnational collaboration has shaped my research identity and deepened my commitment to equity.

1.3 Scholarly and Original Contributions

This section provides an integrated account of my scholarly development and individual contributions across the ten peer-reviewed publications included in this thesis.

Early contributions: My initial roles as RA on ROSHNI-D and LMIC studies (2012–2016) involved qualitative interviewing, transcription, translation, and qualitative analysis. These roles provided critical insight into idioms of distress, stigma, and relational dynamics shaping maternal mental health in BSA communities. I contributed to manuscript drafting, supervised LMIC qualitative teams, and revisited early feasibility data to document the origins of the PHP intervention. These experiences formed the conceptual foundation for my later work, particularly my understanding of cultural adaptation, epistemic justice, and the relational nature of research participation. They also developed the initial learning for the thesis's conceptual

[5] The trial was originally multi-centre across these 5 study sites, Glasgow was closed early due to low recruitment rates and the full trial then proceeded with 4 study sites.

originality: advancing cultural humility from a clinical stance to a research methodology that addresses power, reflexivity, and shared understanding.

Mid-career contributions: As Deputy Trial Manager and later Trial Manager on ROSHNI-2 (2016–2020), my role expanded substantially. I designed and led the culturally adapted recruitment model, developed bilingual facilitator training, embedded cultural humility principles into governance and fidelity processes, and coordinated multi-site delivery. I contributed to intervention refinement, nested qualitative work, and operational decision-making. My first-authored publication ***(Lunat et al., 2020)*** marks a turning point in my scholarly development, demonstrating how cultural humility can be operationalised within NIHR trials to strengthen methodological inclusivity. These contributions underpin the thesis's methodological originality: practical, transferable models for embedding cultural humility across different research infrastructures. While demonstrated within large-scale NIHR trials, the principles developed here: community-mediator roles, community-led engagement strategies, culturally grounded governance processes, and facilitator training frameworks are not tied to a single trial design. Instead, they offer a flexible approach that can be adapted to varied research settings, provided they are implemented with attention to local cultural contexts and power dynamics. This positions cultural humility as a methodological stance that guides how research systems can be reshaped to support equity and illuminate women's voices.

Senior leadership contributions: In my senior leadership roles (2020-2026), reflected in publications such as ***Lunat et al. (2020)***, ***Husain, Lunat et al. (2024)***, ***Husain, Lovell et al. (2025)***, and ***Ullah, Lunat et al. (2025)***, I held responsibility for trial delivery, recruitment, training, data quality, community involvement, and implementation learning across a multi-site NIHR programme. I contributed substantial sections of these manuscripts, was joint first author or corresponding author, and led the integration of cultural humility into governance structures, fidelity frameworks, therapy delivery, and the embedded economic evaluation. These roles demonstrate my progression into an independent researcher capable of shaping methodological practice, influencing policy, and contributing to national research infrastructure.

These contributions underpin the thesis's originality: demonstrating that achieving equity requires redesigning research structures, not simply adapting interventions.

Although evidenced within NIHR trials, the approaches developed, such as culturally grounded governance, inclusive recruitment pathways, community-led engagement, and facilitator training frameworks, offer transferable models for strengthening equity across wider research environments. Cultural humility is positioned as a methodological stance that can guide system-level change beyond any single trial, provided it is implemented with attention to local cultural contexts and power dynamics.

Global learning and reverse innovation: A central dimension of my scholarly development emerged through the global partnership underpinning ROSHNI-D and ROSHNI-2. These trials were informed by earlier work in Pakistan, where task-sharing models, community-embedded delivery, and culturally grounded communication had already demonstrated effectiveness in maternal mental health care. Insights from these LMIC settings helped to strengthen recruitment pathways, facilitator training, and intervention delivery for BSA women. This bidirectional learning challenges traditional assumptions about the direction of global knowledge transfer, which often presumes that innovation flows from high-income to low-income settings. Instead, the ROSHNI trials demonstrated how LMIC-led approaches can meaningfully inform UK research systems, particularly in relation to equity, trust, and cultural humility. The movement of ideas between Pakistan and the UK, rather than in a single direction, constitutes the thesis's global originality and situates this work within wider debates on decolonising research systems.

Coherent contribution to knowledge: Together, these contributions form a coherent and original body of work that advances knowledge on cultural adaptation, community-centred research, global learning, and structural equity in maternal mental health. They demonstrate how my evolving roles from early qualitative work to senior leadership produced a conceptual and methodological contribution: cultural humility as a framework capable of reshaping research systems so that they better reflect the realities, needs, and knowledge of BSA communities.

Figure 1 - Overview of Research Journey and Scholarly Progression

From Research Assistant to Research Leader - My Research Journey

2026: ROSHNI-3 - NIHR Programme grant proposal April 2027 - March 2032

2026: Research Leader
Leading with cultural humility and community trust

Non-Specialist Workforce

Community-Embedded Delivery

Family-Inclusive Consent

ROSHNI-2

Language-Matched Recruitment

Primary outcomes

- Earlier recovery and greater symptom reduction in the PHP group at 4 months.
- Sustained improvements at 12 months
- High acceptability + feasibility
- Non-specialist delivery effective

Culturally Adapted Content

Who we reached

- 9136 women assessed
- 4296 eligible and consented
- 732 randomised
- High retention across both arms

Conversational Screening

2016 - 2022: ROSHNI-2 Trial delivery

2016 - 2024: Trial Manager

2016: Deputy Trial Manager

ROSHNI-D March 2011 - October 2013:
Exploratory RCT of a group psychological intervention for postnatal depression in British mothers of South Asian origin.

2012: Research Assistant
Research Assistant on ROSHNI-D

2012: Graduated from Masters at University of Lancashire

The thesis is organised into five chapters. Chapter 2 sets out the epidemiological, cultural, and structural landscape of PMH for BSA women and introduces cultural humility as the guiding framework for the thesis. Chapter 3 traces how this framework was embedded through cultural adaptation, engagement, and implementation of the ROSHNI trials in the UK, showing how learning from each stage shaped the final model. Chapter 4 turns to global mental health learning, highlighting bidirectional exchange with Pakistan. Chapter 5 brings these strands together, synthesising the contributions to knowledge, practice, and global mental health, and outlining future directions for research, policy and system change. Cultural humility runs through every chapter, shaping the methodological reflections and the model of community-engaged research developed across this thesis.

CHAPTER 2 – SETTING THE SCENE: MATERNAL MENTAL HEALTH INEQUITIES AND CULTURAL HUMILITY

2.1 Chapter introduction

This chapter sets the contextual and theoretical foundations for this thesis. Despite significant investment in PMH services and growing policy attention in the UK, persistent inequities in access, engagement, and outcomes remain. Here, I examine what the problem is, what has been attempted, and why existing approaches have not adequately addressed the needs of BSA women. Drawing on external literature and my own publications, I describe how stigma, izzat (family honour), gendered family dynamics, and confidentiality fears intersect with structural racism, migration histories, and systemic exclusion to produce both elevated risk and reduced visibility in services. These barriers help explain why BSA women remain underrepresented in both research and clinical care despite evidence of higher symptom burden.

2.2 Maternal Mental Health Inequities

Maternal mental health disorders, including antenatal and postnatal depression, anxiety, post-traumatic stress disorder, and postpartum psychosis, affect an estimated 10–20% of women globally (WHO, 2022; Howard et al., 2020). These conditions have significant implications for maternal wellbeing, infant development, and long-term family health (Bauer et al., 2014).

Research consistently demonstrates that BSA women experience a higher burden of PMH difficulties than the general population (Edge, 2010; Prady et al., 2016; Pilav et al., 2022). Large-scale cohort studies, including Born in Bradford, have shown elevated rates of depressive symptoms among Pakistani and Bangladeshi women, shaped by factors such as socioeconomic disadvantage, migration stress, limited social support, and cultural expectations around motherhood (Prady et al., 2016; Jankovic et al., 2020). These findings align with global evidence showing that migrant and ethnic minority women face increased vulnerability to PMH disorders due to cumulative stressors, discrimination, and reduced access to culturally responsive care (Fellmeth et al., 2017).

The most recent MBRRACE-UK Perinatal Mortality Surveillance Report (2025) continues to highlight stark and persistent ethnic inequalities in maternal health outcomes across the UK. South Asian and Black women remain significantly more

likely to experience severe maternal morbidity and adverse perinatal outcomes compared to White women, with structural racism, delayed access to care, and communication barriers identified as key contributing factors. These findings reinforce the urgency of the work presented in this thesis.

Despite this elevated risk, BSA women remain under-represented in PMH services. Studies consistently report lower referral rates, reduced access to psychological therapies, and poorer recovery outcomes for ethnic minority women (Jankovic et al., 2020; NHS Race & Health Observatory 2023). Under-representation is shaped by multiple systemic barriers, including limited availability of culturally appropriate services, lack of linguistic support, diagnostic mismatch, and mistrust of statutory services (Edge, 2010; Pilav et al., 2022). These inequities persist despite major national investments. The NHS Long-Term Plan (2019) committed to expanding specialist PMH services, and the renewed Women's Health Strategy (2026) emphasised reducing inequalities in maternal outcomes. Recent UK parliamentary proceedings show substantial increases in PMH funding (UK Parliament, 2025). Yet evidence indicates that these investments have not translated into equitable access or outcomes for women from minority backgrounds, highlighting a persistent gap between ambition and meaningful inclusion.

2.3 Stigma, Izzat and Structural Barriers

Stigma surrounding mental illness remains a significant barrier to help-seeking among BSA women. Mental distress is often framed in moral, spiritual, or physical terms, contributing to silence, shame, and delayed help-seeking (Edge, 2010). The cultural construct of izzat plays a central role in shaping emotional expression and help-seeking behaviours. BSA women may conceal symptoms of mental health difficulties to protect family reputation, avoid gossip, or maintain harmony within extended households (Thomson et al., 2022).

Family dynamics further shape visibility and access. In many BSA households, decisions about healthcare are collective, influenced by partners, mothers-in-law, and extended family members. Confidentiality fears are heightened in tight-knit

communities, where being seen accessing mental health support may carry social consequences (***Masood et al., 2015***; Miah et al., 2025[6]).

This narrative was further strengthened from the perspectives of General Practitioners (GPs) who were interviewed as part of the nested qualitative study on ROSHNI-2 ***(Husain, Lovell et al, 2025)***. The GPs reflected that culture had a strong influence on the way the women presented their problems in clinic.

"Well, it's interesting, the people from the Asian communities will present things in a different way, whereas people from the white community may come and tell you things much more straightforward". *GP LO-005*

Experiences of racism and unfamiliarity with NHS pathways also contribute to mistrust and disengagement (Thomson et al., 2022; Pilav et al., 2022). Migration-related factors, including cultural bereavement, loss of social networks, discrimination, and the strain of navigating unfamiliar systems continue to shape women's experiences of distress and access to care. Recent evidence shows that migratory grief is strongly associated with psychological distress (Renner et al., 2024), and that cultural bereavement can heighten post-migration stress, particularly when compounded by discrimination or weak community integration (Fatima & Musharraf, 2026).

2.4 Cultural humility as the conceptual framework

Cultural humility provides a conceptual lens for understanding and addressing the inequities outlined in this chapter. As introduced in Chapter 1, cultural humility (Tervalon & Murray-Garcia, 1998) emphasises lifelong learning, self-reflection, and recognising power imbalances within clinical and research encounters. Unlike cultural competence (Kirmayer LJ, 2012), which implies that culture can be mastered or acquired, cultural humility foregrounds openness, accountability, and partnership, acknowledging that individuals and communities are the experts in their lives.

Research has expanded cultural humility in ways that are highly relevant to PMH research. Narrative humility (DasGupta, 2008) highlights the importance of listening to the stories people tell about their distress, recognising the limits of one's own

[6] Co-authored qualitative paper, included in Appendix C but not included in published works for this thesis.

interpretive frameworks, and approaching each encounter with curiosity rather than assumptions.

Structural competency (Metzl & Hansen, 2014) complements cultural humility by shifting attention from individual-level cultural differences to the structural forces, racism, migration policy, socioeconomic inequality, and institutional bias that shape health outcomes. Structural competency argues that clinicians and researchers must be able to recognise how structural conditions produce vulnerability, mistrust, and differential access to care (Bourgois et al., 2017).

Cultural safety extends beyond cultural competence by shifting the focus from the practitioner's knowledge to the service user's experience of care (Curtis et al., 2019). The concept originated in Aotearoa/New Zealand within Māori nursing scholarship, to highlight power, equity, and the need to address institutional racism within health systems. Unlike cultural competence, which risks reducing culture to a tick-box activity, cultural safety requires organisations and healthcare professionals to create environments in which individuals feel respected, heard, and free from discrimination. Cultural safety is a useful framework for addressing racialised inequities in maternity care and improving trust and engagement among ethnic minority women (Knight et al., 2023).

Recent literature has applied cultural humility to PMH specifically, arguing that culturally responsive care requires attention to gendered expectations, family dynamics, and the sociocultural meanings of motherhood (Edge, 2010; Konidaris & Petrakis, 2025). Cultural humility therefore provides a framework for understanding not only how women express distress, but how they navigate stigma, family honour, confidentiality concerns, and structural barriers when seeking support. The next chapter demonstrates how these principles informed the design, delivery, and implementation of the ROSHNI trials and the wider impact of the trials.

CHAPTER 3: CULTURAL ADAPTATION, ENGAGEMENT AND IMPLEMENTATION (UK FOCUS)

3.1 Overview of the ROSHNI Trials and stages of development

The work and learning on the ROSHNI trials grew in stages, shaped by the women who took part and by the questions each study left unanswered. Following the Medical Research Council (MRC) framework for developing and evaluating complex interventions (Skivington et al., 2021), the work began with a small development and pilot study (***Khan et al., 2019***), where the earliest version of the PHP was tested and refined. This was followed by an NIHR Research for Patient Benefit (RfPB) funded exploratory trial, ROSHNI-D (***Husain et al., 2023***), which allowed us to understand how the intervention worked in practice, and the factors to consider in recruiting and retaining BSA women to a trial. These early studies revealed patterns that could not be ignored: the importance of language, the weight of family dynamics, the role of stigma, and the need for research encounters that felt safe and culturally grounded. By the time we reached the large multicentre clinical and cost-effectiveness trial (***Husain, Lovell et al., 2022; Husain, Lunat et al., 2024; Husain, Lovell et al., 2025; Ullah, Lunat et al., 2025***), guided by lived experience experts, cultural humility had become the practical lens through which every aspect of the trial was designed and delivered.

The ROSHNI trials were shaped in parallel with work in Pakistan, where community-delivered psychological interventions had already demonstrated strong outcomes in low-resource, high stigma settings (***Husain et al., 2017***, Rahman et al, 2013). This bidirectional learning is explored in more detail in Chapter 4.

3.2 Cultural humility as the foundation for adaptation

Across these stages, cultural humility became the thread that held the programme together. It required a commitment to flexibility that moved beyond ‘business as usual’ practices that typically felt ‘easy’ and comfortable based on how we had been trained to work. It required changes to governance, ethics, training, and fidelity procedures to ensure that cultural humility was not simply talked about but fully integrated and practiced. This chapter describes how this was practiced and how each stage of the ROSHNI journey contributed to a model of culturally adapted research that was both rigorous and rooted in the community.

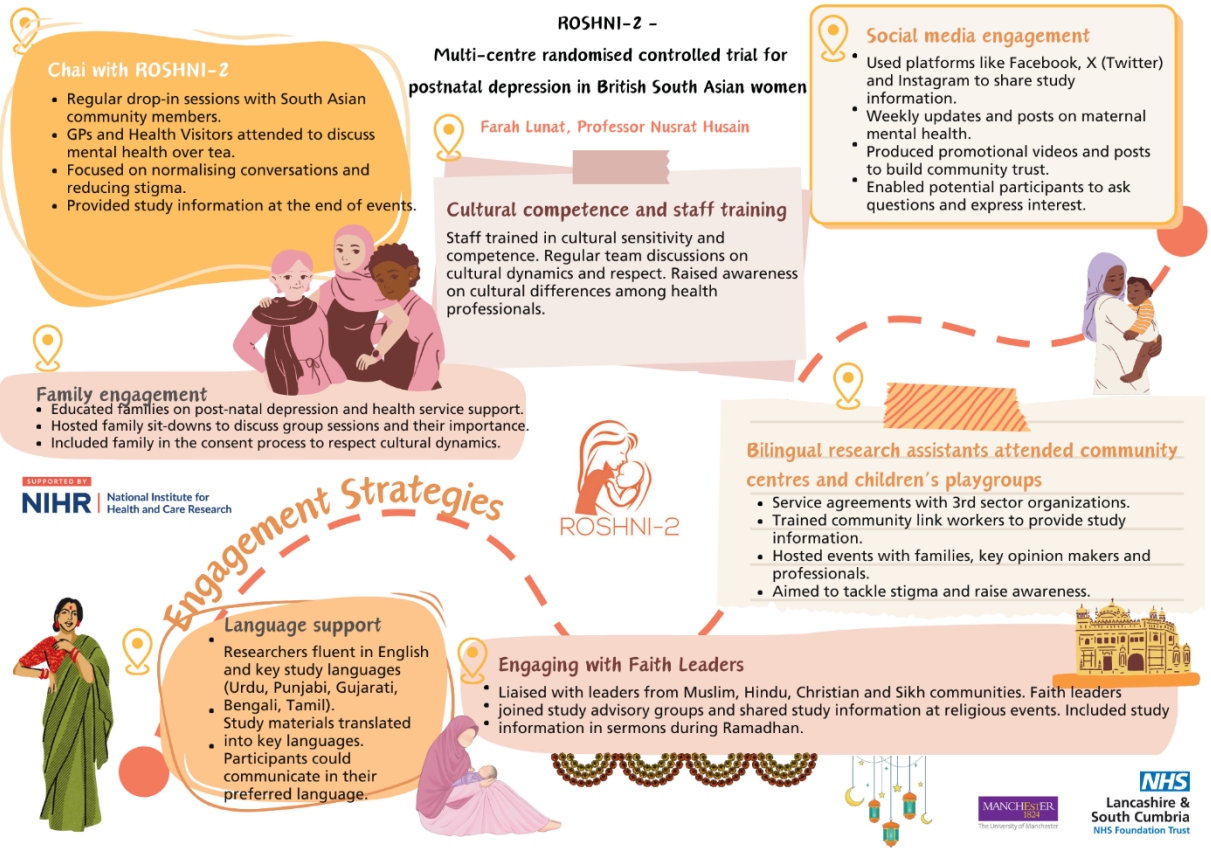
The ROSHNI trials had nested qualitative studies included in which semi-structured interviews were carried out with participants, RAs and PHP facilitators. These interviews described similar shifts moving from competency to humility (***Masood et al, 2015***; Miah et al., 2025). Cultural humility could not be taught through manuals or training, it was practised through presence, patience, and respect, as part of an ongoing learning journey. This approach reflects what DasGupta (2008) calls narrative humility, the ethical stance of being receptive to others' stories without assuming authority over them. Narrative humility allows researchers and practitioners to hear the multiple truths that coexist within a community and to resist the impulse to categorise or correct. In the context of MMH, it invited us to see each story as both personal and political, shaped by structures of culture, gender, migration, and faith, and by the everyday negotiations women make to preserve their dignity, belonging, and safety. In ROSHNI-2 for example, there was a built-in internal pilot. As part of the pilot, the study team conducted qualitative interviews, and one participant stated – "I was a bit reluctant to tell my mom that I have joined the group. . . because she is from the old school of thought and anything about mental health is very stigmatising for her. Also, she will not like that her daughter is suffering from depression nor has any mental health issue" *(trial participant NW-13-0030) (Husain et al, 2025)*. This insight from the internal pilot reinforced the importance of ongoing reflexivity within the research team and highlighted the need to adapt our approach in response to women's lived realities. In this case, it prompted a stronger emphasis on family involvement and engagement. While this thesis focuses on "South Asian" women, a critical reflection on the work, particularly ***Husain, Lunat et al. (2023),*** requires an acknowledgement of the risks of cultural essentialism. "South Asian" is often treated as a monolithic category, yet the women who participated in the ROSHNI trials represented diverse intersections of religion, migration histories, socioeconomic status, and generational acculturation. In leading the recruitment and adaptation phases, I moved deliberately beyond a "one size fits all" model by focusing on these nuances. Linguistic adaptation, for example, was not a simple translation; it required navigating dialectal differences also. This approach aligns with intersectionality frameworks (Crenshaw, 1991) and critiques of cultural essentialism in global mental health (Kirmayer, 2012), positioning cultural adaptation not as a static product but as a dynamic process.

Listening and focusing on detail, in this sense, became a form of accountability for me as a researcher. It required me to adapt our methods and design research that honoured the realities women shared with us. It also laid the foundation for the creative and community-led approaches explored in the sections that follow.

3.3 Key strategies for engagement, recruitment and adaptation

Below is a visual representation highlighting key strategies employed across ROSHNI-2. Further detail is provided in Appendix A which showcases the full range of engagement activities and is also documented in ***Husain, Lunat et al. (2024).***

Figure 2 – Visual representation of key engagement strategies used on the ROSHNI-2 trial



Patient and Public Involvement and Engagement (PPIE) was central to the design and delivery of ROSHNI-2, aligning with NIHR guidance that research must be shaped with communities rather than delivered to them (NIHR 2019; NIHR INCLUDE, 2020). For populations historically underrepresented in research, meaningful involvement requires early, sustained, and culturally grounded engagement. In ROSHNI-2, PPIE informed every stage, from grant development to recruitment, delivery, and dissemination and provided the foundation for a community-centred approach.

3.3.2 Community Engagement and Visibility

Recruitment in ROSHNI-2 had to begin with education, visibility, and trust. From the previous trials, I knew that we could not rely on primary care referrals or standard recruitment pathways. In communities where stigma, mistrust, and limited awareness shape help-seeking, engagement must start long before a research invitation is offered. Women needed to see us, recognise us, and understand why we were doing this work. A stakeholder from a community organisation that was well-trusted within Lancashire told me very early on that for the project to work, it needed a 'face'; we needed to establish ourselves in the community as trusted individuals.

The recruitment model described in ***Lunat et al. (2020)*** was therefore operationalised across all sites. Bilingual RAs were present in GP surgeries, children's centres, immunisation clinics, and voluntary sector venues. I was responsible for preparing the training materials for these researchers and coordinated with the wider co-applicant team to support capacity building. The RA role was to publicise, recruit and assess participants for the trial. Each RA was able to speak at least one of the South Asian languages specified in the protocol (Urdu, Punjabi, Hindi, Gujarati, Bengali and Tamil).

3.3.3 "Chai with ROSHNI": Creating Safe, Familiar Spaces

The informal drop-in sessions, "Chai with ROSHNI", in friendly community settings such as Children's Centres, cafes and community centres created open, familiar spaces where women could ask questions safely and in a language of their choice. These were informal, conversational spaces where women could talk openly about traditions such as the 40-day postpartum confinement, food practices, family expectations, or the pressures of living in extended households. We invited health visitors and midwives to these sessions so they could hear directly from women. It also encouraged health visitors and midwives to practice cultural safety described earlier. In one of these sessions, an individual described their birthing experience. She described how she was on the ward prior to labour and experiencing a lot of pain, a midwife had said to her "your lot can't handle any pain". She described how she felt judged and like she was 'weak' and it meant she kept hesitating to ask for anything else. These conversations helped me capture the everyday realities that often sit outside formal assessments we use in routine practice in research and maternity services. The purpose of these sessions was to encourage community conversation on MMH, with the idea that education has the power to diminish stigma. We also

encouraged feedback on our approaches within these sessions so that the study methods could be adapted if needed.

3.3.4 Community Partners as Trusted Intermediaries

Community partners from local organisations and faith groups acted as trusted intermediaries, helping us reach women who might otherwise remain invisible to research. Through the lens of cultural humility, we recognised that many BSA families seek support from places they already trust, such as community centres and faith settings. These spaces therefore became essential allies in raising awareness, sharing information, and giving women the opportunity to learn about the study and make informed choices. Our activities were documented ***(Lunat et al., 2020)*** and continuously monitored and refined. I was intentional about recording these approaches because they offer practical, replicable methodological steps that can strengthen inclusivity and accessibility for seldom-heard communities.

3.3.5 Practical supports to enable participation

Visibility and presence were paired with practical supports built in to minimise barriers to participation. Timing eligibility screening around existing GP appointments, offering childcare and travel reimbursement to support participation (included in the funding), and ensuring that first contact felt warm and culturally grounded. The presence of bilingual RAs who could deliver conversational screening in a language of choice was critical. It allowed women to speak in their own metaphors, and it allowed us to map those narratives onto standardised measures without forcing them into forms of expression that felt unfamiliar or unsafe (***Lunat et al., 2020***). The trial collected qualitative data from withdrawn participants (with ethical approval) to understand barriers to taking part in the study. Findings (Miah et al., 2025) highlighted family pressures, confidentiality concerns, and competing responsibilities. These insights informed adaptive retention strategies e.g., offering alternative session times, enabling family-inclusive conversations, and providing discrete routes for participation that reduced attrition.

3.3.6 Community Advisory Groups: Shared Ownership

Another strand of involvement was the establishment of ROSHNI-2 Advisory Groups in each study site. The first group began in Blackburn, East Lancashire, where I had longstanding relationships through ROSHNI-D and wider research roles. I brought

together community leads, faith leaders, midwives, GPs, school staff, individuals with lived experience, and voluntary sector partners. I drafted the terms of reference, set agendas, and facilitated the early meetings, then invited members to choose a Chair from within the group so that leadership felt genuinely community-owned. These meetings became spaces where people spoke openly about stigma, mistrust, and the realities of navigating mental health within BSA communities. Their insights helped us understand the nuances between different geographical areas and why a single approach would never work across all communities. The minutes from these meetings show how wide-ranging and practical the discussions were in supporting our recruitment approach, impact and dissemination activities and broadly improving awareness and education of MMH. They suggested connecting with mosques and Taleem classes (educational sessions for women in the mosques), training mosque leaders in Mental Health First Aid, designing materials for fathers, engaging domestic violence organisations, and planning community events around Time to Talk Day[7], Maternal Mental Health Awareness Week[8] and International Women's Day[9]. These advisory groups shaped real decisions for methodology and dissemination. When members recommended placing materials in Asian businesses, we did so. When they suggested Friday sermons during Mental Health Week or Ramadhan, we explored those routes. When they raised concerns about literacy or confidentiality, I revised materials through ethical amendments and fed back to the group. Five advisory groups were convened in total across the four study sites, each meeting regularly to review progress and ensure the study remained grounded in local realities. The CI or I were active members on each of the groups so we could listen and learn. This structure reflected cultural humility and the principles of authentic participation (Cargo & Mercer, 2008) and NIHR INVOLVE guidance (2019), recognising that expertise sits within communities.

3.3.7 Lived Experience Leadership in PPIE

Our PPIE lead, who had participated in ROSHNI-D, worked with me from grant development through to dissemination. She helped refine language, anticipate how

7https://www.mind.org.uk/get-involved/time-to-talk-day/

[8] Maternal Mental Heath Awareness Week is a week-long campaign dedicated to talking about mental health problems before, during and after pregnancy. It is led and coordinated by the Perinatal Mental Health Partnership and I am one of the founding members of this group.

[9] https://www.un.org/en/observances/womens-day

materials might be interpreted, and ensure that processes felt respectful and culturally appropriate and meaningful. In the early stages of the study, she supported to refine all participant facing materials and attended the ethics committee meeting with me and the CI. She also co-facilitated some RA training sessions, helping staff understand not only what to say but how to say it.

Her insights along with the individuals with lived experience in the advisory group helped us to adapt our recruitment approach and materials through ROSHNI-2 trial. For example, following the completion of the internal pilot, feedback was to have a stronger focus on family engagement and so we designed new promotional materials including fathers and wider family in the messaging. All study materials are included in the supplementary materials published in ***Husain, Lovell et al, 2025***.

3.3.8 Assessment adaptation: conversational screening and cultural validity

Standardised assessment tools such as the Patient Health Questionnaire (PHQ-9), a nine-item measure of depressive symptoms, and the Generalised Anxiety Disorder scale (GAD-7), a seven-item measure of anxiety, are widely used in clinical trials to assess symptom severity. As Kleinman (1983) notes, distress is interpreted through cultural lenses. Western tools assume familiarity with biomedical constructs of mood, guilt, and emotional experience, which may not align with how BSA women articulate suffering. Their descriptions of distress often draw on relational, familial, and spiritual frameworks, creating a mismatch between lived experience and the terminology embedded in Western diagnostic systems. During the early stages of ROSHNI-2 recruitment, I noticed a pattern that raised concern: a large number of PHQ-9 forms were being returned with total scores of zero, indicating no depressive symptoms. This did not align with what we knew about the population or the clinical context. Drawing on my qualitative work in ROSHNI-D ***(Masood et al., 2015)*** and ongoing conversations with our PPIE representative, I convened team discussions to explore why women were not comfortable completing the PHQ-9 as a self-report measure. Many lacked the cultural vocabulary to express distress in the way the PHQ-9 required, and ticking boxes about guilt or suicidal ideation felt unsafe. Our PPIE lead also advised due to immigration concerns people are always wary of filling in paperwork and not knowing where it is going. I proposed a revised screening process grounded in cultural humility as result of this feedback. In consultation with the CI,

wider co-applicant team and advisory boards we submitted an ethics amendment. Instead of relying on written self-report, we shifted to a conversational delivery of the PHQ-9. Researchers guided participants through each item, taking time to build rapport, explain the purpose of the questions, and normalise emotional expression. This approach allowed women to articulate distress in their own terms while still enabling us to map their experiences onto the PHQ-9. These adaptations were approved via an ethics amendment and incorporated into a revised trial protocol[10].

3.3.9 Training and governance

I led the development and delivery of the training programme for RAs across all four ROSHNI-2 sites, ensuring that cultural humility was embedded into every stage of assessment. The training combined practical skill building with reflective practice, role-plays, guided discussions, and supervision sessions helped staff recognise how women might express distress indirectly and develop confidence in exploring sensitive topics in ways that felt respectful and safe. Learning from our Pakistan collaborators was central to this process ***(Husain et al 2017)***. Their extensive experience of conducting assessments in high -stigma, low -literacy contexts offered valuable insights into how to explain concepts that do not translate directly between Urdu and English and how to adapt phrasing without losing clinical meaning.

Small but meaningful nuances were also incorporated into the training. For example, I encouraged RAs to dress casually when visiting women at home if they were comfortable to do so. This was based on feedback in the earlier ROSHNI-D trial, where a participant described feeling intimidated when an RA arrived in formal workwear, as though her home or appearance needed to meet a certain standard. Encouraging RAs to "meet women where they were", not only in location but in presence, tone, and relatability became a core principle of our approach.

To maintain safety and consistency, assessment procedures were monitored through fidelity checks and regular team meetings, where researchers could reflect on challenges, share learning, and refine their practice. I held team meetings usually in a café to have a relaxed atmosphere and encourage RAs to be open about their

[10] Study protocols are published on the NIHR website - https://www.fundingawards.nihr.ac.uk/award/14/68/08 this includes detail on all ethical amendments.

experiences in the community and ensuring they were comfortable with working in this culturally adapted style of delivery.

3.3.10 Family engagement and household dynamics

In many BSA households, decisions about healthcare and research participation are negotiated collectively. As discussed in Chapter 2, izzat (family honour) shapes disclosure and can make help-seeking risky for women. Rather than treating family influence as an obstacle, ROSHNI-2 engaged families as potential allies. Where appropriate and with the woman's consent, researchers met with partners, mothers-in-law and other family members to explain the intervention framed in terms of family wellbeing and child outcomes. Information sessions were framed around parenting, relationships and practical support rather than diagnostic labels. Family-inclusive consent conversations were used to reduce suspicion and to negotiate confidentiality in culturally humble ways that respected household norms while also respecting women's autonomy. Embedding family engagement required careful ethical consideration; I trained the researchers to ensure that family involvement did not coerce participation, to protect confidentiality, and to support women's own power and control. During one home visit for screening and consent, over a dozen family members joined the session and asked questions. While I engaged with them and addressed their concerns, it was clear the participant had no privacy or space to speak for herself. I therefore chose not to take consent at that time and instead identified a quieter opportunity. I later arranged to meet her at the GP practice after a routine appointment, ensuring her family felt respected while also giving her protected one-to-one time to understand the study and provide informed consent. Family-inclusive approaches reduced barriers to attendance in PHP sessions/ Qualitative data (***Masood et al.***, 2015; Miah et al, 2025) indicate that when families understood the intervention's focus on wellbeing and child outcomes, they were more likely to encourage attendance to sessions or completion of study assessments.

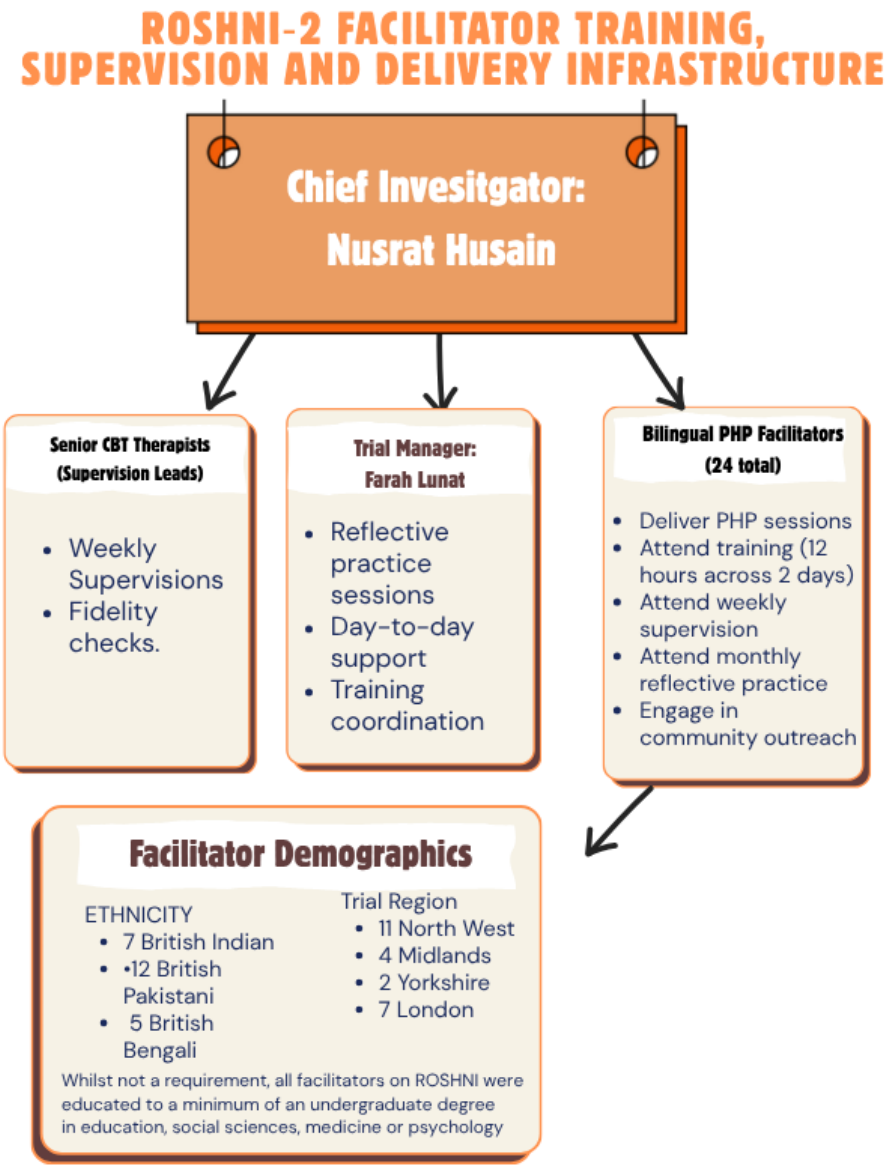
These activities contributed to large-scale engagement, ROSHNI-2 screened over 4,000 women and randomised 733 participants across multiple sites, demonstrating that culturally adapted recruitment can achieve scale without sacrificing ethical sensitivity or participant safety ***(Lunat et al., 2020; Husain, Lunat et al., 2024).***

3.3.11 Adaptation of therapy: content, metaphors and facilitator model

Cultural adaptation of the PHP moved beyond just translation to ensuring that women could relate to the content. It included metaphors, case vignettes and activities that reflected migration histories, household dynamics, spiritual frameworks and everyday practices. Early qualitative work ***(Masood et al., 2015; Khan et al., 2019)*** identified common metaphors and themes expressed by BSA women that were incorporated into the PHP facilitator manual as examples, homework activities and group exercises. Appendix B describes the content of sessions in the PHP manual and how they were adapted (taken from ***Khan et al 2019*** and ***Husain, Lovell et al, 2025***). Supervisors monitored adherence to core components (behavioural activation, problem-solving, relapse prevention) while supporting facilitators to adapt examples and metaphors responsively.

Drawing on learning from the Pakistan trials ***(Husain et al., 2017)***, where community health workers successfully delivered psychological interventions in low-resource, high-stigma settings. The PHP in ROSHNI-2 was delivered by bilingual facilitators in a group setting in a neutral community venue. Each group was delivered by two facilitators. They were non-specialist workers, who were trained NHS band 4–7 researchers, with backgrounds in psychology, social sciences, or relevant community experience, but no experience in delivering CBT. A total of 24 facilitators (see Figure 3) were trained through a structured programme that included CBT-based techniques, cultural humility, reflective practice, and trial-specific procedures. Training was delivered over 2 days, with ongoing weekly supervision provided by senior CBT therapists and monthly reflective practice sessions that I facilitated. There were also additional refresher sessions every 6 months during the trial recruitment period. This model ensured cultural and linguistic alignment with participants, but it also required sustained investment in training, supervision time, and emotional support for facilitators discussed in detail in ***Husain, Lovell et al., 2025***.

Figure 3 - ROSHNI-2 Facilitator Training, Supervision and Delivery Infrastructure



While effective, this facilitator model also carried important limitations and implementation considerations. Delivering PHP through non-specialist staff required sustained investment in training, supervision time, and emotional support, which has implications for scalability and workforce planning. The two-day training, supplemented by refreshers, was sufficient for fidelity but required ongoing oversight from senior CBT therapists. The economic implications of this facilitator model are detailed in the ROSHNI-2 health economics evaluation ***(Ullah, Lunat et al 2025)***. The analysis demonstrated that training and supervising community-based facilitators was a relatively low-cost component of the intervention, with costs primarily driven by initial training, ongoing supervision time, and facilitator delivery hours. Importantly, the economic evaluation found that the PHP remained cost-effective even when

accounting for these training and support requirements, reinforcing the feasibility of scaling a non-specialist workforce model within NHS maternity mental health pathways.

3.4 ROSHNI-2 during COVID19

The COVID-19 pandemic (2020-2023) introduced new challenges and new learning. As services shifted to remote delivery, many BSA women faced digital exclusion, limited devices, low data, low confidence with technology, and concerns about privacy in multigenerational homes. Working closely with our PPIE leads, I gathered rapid feedback through one-to-one calls and an urgent group consultation to understand what would help women stay engaged. Their guidance shaped a series of simple, practical adaptations: providing earphones for privacy, creating WhatsApp videos to demonstrate how to join group PHP sessions, offering tips on using the chat function when speaking aloud felt unsafe, and agreeing clear plans for what to do if someone entered the room unexpectedly. These adjustments, grounded in lived realities, ensured the intervention remained accessible and safe during the pandemic. This experience reinforced that equity requires more than offering digital options, it requires designing digital pathways that are culturally, practically, and emotionally accessible. It also demonstrated that meaningful adaptation could happen quickly when guided by community insight.

3.5 Dissemination and impact: participatory, culturally humble knowledge translation

Cultural humility was also applied to underpin dissemination and impact activities. One example was a participant journey video I organised with the Clinical Research Network (CRN) (now named as Research Delivery Networks). Some women who had participated in the study wished to contribute but did not want to be visually identifiable. We worked with the CRN to film group circle arrangements and audio-only segments that allowed women to share their experiences without exposing their faces. This approach respected cultural preferences while ensuring that lived experience informed public narratives.

Following publication of the main trial results in *The Lancet* ***(Husain, Lunat et al., 2024),*** I invited a participant who had expressed interest in stigma reduction work to join the CI and me on *The Lancet* podcast (links to all media outputs in Appendix A).

I met with her before and after the recording to ensure the process was culturally appropriate and empowering. I hoped to ensure that public dissemination amplified a lived experience voice in a way that felt safe.

Social media, television and radio presence and community events such as sharing the findings during mental health events were used not simply as dissemination tools but more as a means of knowledge coproduction that fostered visibility, belonging, and cultural resonance. The cumulative impact of the ROSHNI-2 trials and its creative engagement strategies has begun to shape national conversations on inclusive PMH care. Reflecting this growing recognition, in 2019, I was invited to write a section on ROSHNI as a best practice example for the Improving Access to Psychological Therapies (IAPT), Black and Asian Minority Ethnic (BAME), Positive Practice guide (https://lewishamtalkingtherapies.nhs.uk/wp-content/uploads/2021/10/IAPT-BAME-PPG-2019.pdf). The guide is used to improve access, engagement, and treatment outcomes for BAME communities within NHS Talking Therapies (formerly IAPT). It helps clinicians provide culturally sensitive care, reduces DNA (Did Not Attend) rates, and ensures equitable service provision. Furthermore, the ROSHNI-2 trial's health economics analysis ***(Ullah, Lunat et al., 2025)*** provided robust evidence that culturally adapted, community-embedded care can be cost-effective within existing budgets.

The next chapter explores how these UK-based lessons informed and were informed by global partnerships, and how bidirectional learning between the UK and Pakistan generated innovations that travel in both directions.

CHAPTER 4: GLOBAL LEARNING, BIDIRECTIONAL INNOVATION AND IMPACT

The ROSHNI trials were shaped by a continuous exchange of ideas, practices, and learning between the UK and Pakistan. This chapter explores how global mental health partnerships informed the design and delivery of ROSHNI-2, how learning travelled in both directions, and how the trials generated wider impact across research, practice, policy, and community settings. This collaboration also had a profound influence on my own development as a researcher. Collaborating with colleagues in Pakistan deepened my understanding of culturally adapted intervention delivery, strengthened my reflexive practice, and expanded my ability to adapt methods, language, and engagement strategies across diverse contexts. It also shaped my development as a research leader as I was involved in supervision of researchers.

4.1 Global–Local Partnerships and Impact

The ROSHNI model was built on a longstanding partnership between UK and Pakistan research teams, grounded in shared values of cultural humility, community engagement, and equitable access to care. The trials on THP (Rahman et al, 2008) and LTP Plus in Pakistan ***(Husain et al, 2017)*** demonstrated that culturally adapted CBT delivered by non-specialist community health workers could achieve recovery in three out of four women with perinatal depression. This showed that psychological interventions could be effective, scalable, and culturally resonant when rooted in local realities and delivered through trusted community networks.

Bidirectional learning became a defining feature of my development and learning, particularly in applying the concept of cultural humility. As we adapted THP principles for the UK, we also generated insights that travelled back to Pakistan. This involved drawing on the work I contributed to strengthen fidelity monitoring, structured supervision frameworks, and research governance. These approaches are now being integrated into ongoing NIHR-funded global health projects. This two-way exchange reflects a model of global mental health that is collaborative rather than extractive, where learning flows across contexts rather than from “South” to “North”.

4.2 Cultural Humility as a Framework for Global Mental Health

Cultural humility provided the conceptual bridge that connected learning across settings. In Pakistan, cultural humility was expressed through community health

workers who shared language, culture, and lived experience with the women they supported. In the UK, cultural humility required us to recognise the limits of our assumptions, to listen deeply to women's narratives, and to adapt our methods in ways that honoured their realities.

Across both contexts, cultural humility meant:

- acknowledging and addressing power imbalances
- valuing community expertise as central to decision-making
- meeting the needs of communities so often left out of research
- embedding reflexivity into training, supervision, and governance

This framework allowed us to translate principles across settings without assuming that what worked in one context would automatically work in another.

4.3 Extending Impact Beyond the Trial: Strengthening Global Research Capacity

One of the most meaningful aspects of my role has been supporting colleagues in Pakistan to build the confidence, capability, and systems needed to deliver high-quality global mental health trials. My own learning from ROSHNI-2, particularly around UK gold standards for trial delivery, governance, data integrity, and participant-centred practice became the foundation for a wider programme of capacity building across our international partnerships. As Assistant Director for the Global Mental Health and Cultural Psychiatry Research Group, I now lead training that translates these standards into approaches that are both rigorous and contextually grounded. One example of this work was in December 2025, when I travelled to Medina, Saudi Arabia, to deliver training to researchers working on NIHR-funded trials in Pakistan. The training was designed to bridge two worlds: the expectations of UK-sponsored trials, and the realities of delivering research in low-resource, high-stigma settings. Drawing on the lessons of ROSHNI-2, I emphasised not only the technical aspects of trial delivery such as delegation logs, audit readiness, data integrity, and fidelity monitoring, but also the ethical dimensions that underpin culturally humble research. I delivered sessions on research readiness, shared accountability, ethics and governance, participant engagement, data management, and trial closeout. Throughout, cultural humility served as the guiding principle, recognising that while UK standards provide a framework for quality, they must be adapted thoughtfully to local

systems, resources, and cultural norms. What emerged from these sessions was shared understanding that high quality research is not simply about compliance or documentation. It is about creating systems that protect participants, honour their contributions, and ensure that the data generated reflects their commitment. Through this work, the impact of ROSHNI-2 extends far beyond the trial itself. The principles that shaped the programme; cultural humility, community partnership, and rigorous participant-centred research, are now embedded in the training of new researchers, the governance of NIHR-funded trials in Pakistan, and the wider global mental health research ecosystem.

4.4 Ethical Impact and Decolonising Research Practice

My contribution to the *Journal of Medical Ethics* paper (Memon et al., 2025[11]) reflects another dimension of ROSHNI's impact, shaping ethical discourse on culturally responsive and decolonised research practice. Although this paper is not part of the published works included for this thesis, it is an important example of how learning from ROSHNI-2 informed my broader scholarly development. The paper argues that research with underserved communities requires more than procedural ethics, it requires relational ethics grounded in cultural humility, trust, and shared decision-making. Drawing on learning from ROSHNI-2, I contributed insights on the ethical importance of conversational assessment, the role of PPIE in shaping culturally safe research, navigating confidentiality within extended family systems, and the need for flexible, culturally attuned consent processes. A central argument in the paper is the need to decolonise research ethics. This was a lesson I learned directly through ROSHNI, particularly when adapting the consenting process to reflect collectivist cultural norms. The work highlights how ICH Good Clinical Practice (GCP) guidelines, rooted in Western, individualistic models of clinical research, can create challenges for researchers working in LMICs or with collectivist communities in the UK. My contribution to this publication therefore extends ROSHNI's influence beyond PMH into broader debates about equity, ethics, and inclusion in global health research. These applied ethical insights informed the deeper theoretical and philosophical reflections developed in Chapter 5, where I situate cultural humility within decolonising research ethics and epistemic justice.

[11] Co-authored paper – This paper is not included in the formal PhD published works list. Appendix C provides a full list of all my academic publications.

4.6 National Influence: RCPsych Dean's Grand Rounds and NIHR Webinar

A further demonstration of ROSHNI's national impact came through two key platforms: the Royal College of Psychiatrists' Dean's Grand Rounds and an NIHR webinar on global learning in PMH. Appendix A provides links to these recordings. Together, these events positioned ROSHNI-2 as a leading UK example of culturally adapted PMH care and highlighted the wider relevance of its community-engaged, culturally humble approach.

At the Dean's Grand Rounds on *Health Inequalities in Global Perinatal Mental Health* (February 2025), I was invited, alongside Professor Husain (ROSHNI CI), to present ROSHNI-2 as the UK exemplar of culturally adapted PMH care. The event brought together clinicians, commissioners, researchers, and policymakers from across the UK and internationally, and positioned ROSHNI-2 alongside global innovations such as Australia's Electronic Perinatal and Infant Mental Health telepsychiatry model. Presenting at this forum allowed us to articulate not only the clinical and cost-effectiveness findings, but the deeper learning about cultural humility, community partnership, and the practical steps required to reduce inequities in PMH. Several attendees contacted us afterwards to explore how elements of the ROSHNI model could be integrated into their local perinatal pathways, particularly in UK regions with large BSA populations.

The NIHR online webinar offered a different kind of platform: one that focused explicitly on global learning and the transfer of Community Engagement and Involvement (CEI) principles across contexts. I was asked to share the CEI methods from the global component of ROSHNI-2 that had been most valuable in improving access and outcomes for diverse communities in the UK. Drawing on both the Pakistan and UK experiences, I highlighted three principles that consistently made the greatest difference:

- meeting communities where they are
- embedding bilingual and bicultural staff
- coproducing every stage of the research pathway with women and families.

I was also asked to reflect on the universal barriers to MMH care that I have seen across both the UK and Pakistan. Despite the geographical and economic differences,

the barriers were strikingly similar: stigma, silence, fear of judgement, family expectations, and the belief that emotional suffering should be endured rather than spoken about. In both settings, women described feeling that their distress was invisible or dismissed, and that seeking help risked damaging family honour or inviting community scrutiny. These parallels reinforced that cultural humility is not context specific; it is a universal requirement for meaningful engagement. In the webinar, I spoke about how coproduction can help overcome these barriers. Coproduction shifts the power dynamic: instead of designing interventions *for* communities, we design them *with* communities.

Together, these examples demonstrate that my published works described here are not just clinical trials published in academic settings, but more a model of culturally humble, community engaged practice with relevance far beyond the study sites and beyond just MMH. Culturally adapted, coproduced research can transform access, engagement, and outcomes for communities who have long been described as “hard to reach,” when they have simply been easy to overlook. Chapter 4 has shown how ROSHNI’s impact extends beyond the two trials. Through global partnerships, community engagement, ethical leadership, and culturally humble dissemination, the programme has contributed to research, practice, policy, and global health systems. Chapter 5 draws these insights together, highlighting the programme’s overall contribution and setting out the future directions for research, practice, and policy.

CHAPTER 5 - BRINGING THE THREADS TOGETHER: CONTRIBUTIONS TO RESEARCH, PRACTICE AND POLICY CHANGE

The ROSHNI programme has taught me that research is not only about generating evidence; it is about building trust, shifting assumptions, and creating systems that recognise the realities of the people they aim to serve. As I look back across more than a decade of work, what stands out most is how cultural humility has shaped every stage of this journey from the earliest feasibility interviews to national policy conversations. The impact of this work extends beyond academia. Through invited talks, podcasts, and media contributions (evidenced in Appendix A), I have helped shape national conversations about equity and inclusion. These platforms have enabled me to translate research into practice, influence professional discourse, and advocate for systemic change.

5.1 Policy influence

The policy influence of the ROSHNI programme is now becoming visible. The Overton analytics report (Appendix A) shows that ROSHNI-related publications have been cited in eight policy documents across the UK, France, and Sweden, including government reports, national guidance, and thinktank analyses. These citations span MMH, health inequalities, cognitive behavioural therapy, and perinatal care. For me, this policy reach is deeply meaningful. It signals that the work has travelled beyond academic journals and clinical settings; it is beginning to shape how health systems think about access, culture, and equity. Seeing ROSHNI cited alongside national strategies and international policy reviews reinforces that culturally humble research has a place in the wider policy landscape, and that the voices of BSA women are influencing conversations far beyond the trial sites.

5.2 Research outputs and citation impact

Alongside this policy reach, my academic citation profile reflects a parallel and growing influence within the research community. Over thirteen years, I have moved from research assistant to co-applicant on grants and leading on my own grant submissions. I have authored and co-authored eighteen peer-reviewed articles (full list of publications in Appendix C), delivered national and international talks, and contributed to global conversations on equity in PMH. My publications have now

received 315 citations, with an h-index of 8 and an i10-index of 8, demonstrating that the work is consistently used, referenced, and extended by scholars across global mental health, perinatal care, and cultural adaptation research. The sharp rise in citations since 2021 mirrors the increasing visibility of the ROSHNI programme and the relevance of culturally adapted PMH interventions to both UK and international contexts.

5.3 Economic impact and my contribution to the cost-effectiveness evaluation

The economic case for culturally adapted care is equally important. The cost of untreated maternal mental health problems in the UK is estimated at £8.1 billion per annual birth cohort (Bauer et al., 2014). Yet this figure hides the uneven burden carried by women who face language barriers, stigma, insecure work, or limited family support. Many of the women I met during ROSHNI-2 described juggling childcare in overcrowded housing, managing household expectations, and hiding their distress to protect family honour. These experiences show how untreated postnatal depression can deepen financial strain, disrupt relationships, and lead to long-term reliance on crisis services.

The ROSHNI-2 economic evaluation ***(Ullah, Lunat et al., 2025)*** provided the first evidence that culturally adapted interventions can also be economically sound. My role in this evaluation, collecting and cleaning resource use data, liaising with participants, preparing datasets, and working alongside the health economist, expanded my understanding of how impact is measured. I learned how to interpret cost-utility outputs, incremental cost-effectiveness ratios, and Quality Adjusted Life Years (QALYs), and co-authored the paper as joint first author. Our findings showed that early, culturally sensitive support delivered in women's preferred languages reduced escalation, minimised secondary service use, and improved maternal wellbeing. These outcomes mirror wider evidence from the Maternal Mental Health Alliance and the London School of Economics (Bauer et al., 2014), which advocate for preventive, community- informed models of care.

5.4 My position, power dynamics and epistemic justice

5.4.1 Cultural Humility and Power: Theoretical and Philosophical Foundations

Cultural humility is often described as a stance of openness, reflexivity, and lifelong learning, but its deeper significance lies in how it reconfigures power within research relationships. As Foucault (1977) argued, power is not only held by institutions but enacted through everyday practices, classifications, and systems that shape what is recognised as legitimate knowledge. In maternal mental health research, Western diagnostic frameworks, recruitment pathways, and governance structures can reinforce epistemic hierarchies by privileging biomedical interpretations of distress over relational, cultural, or spiritual meanings. Cultural humility challenges these hierarchies by acknowledging the researcher's responsibility to interrogate the assumptions embedded within research systems and to recognise how these assumptions shape participation, interpretation of data, and outcomes.

Levinas (1969) deepens this discussion through his notion of the ethical encounter, highlighting that responsibility emerges through our relationship with the Other and through careful attention to their lived experience. This concept aligns closely with cultural humility, which positions the researcher not as an expert who "knows" culture, but as someone accountable to the communities they work with. In this thesis, cultural humility is explored through practices such as conversational screening, community-mediator roles, bilingual facilitator training, and shared decision-making. These practices embody Levinas's notion of ethical responsiveness by creating space for participants' meanings, values, social and familial contexts to shape the research process.

5.4.2 Decolonising Research Ethics and Cultural Humility

Cultural humility also aligns closely with decolonising research ethics, which challenges the dominance of Western epistemologies and calls for research practices that recognise, respect, and centre community-held knowledge. Decolonial scholars such as Linda Tuhiwai Smith (1999), Sabelo Ndlovu-Gatsheni (2018), and Bhakuni & Abimbola (2021) argue that ethical research requires dismantling extractive practices, interrogating whose knowledge is privileged, and creating conditions in which marginalised communities can shape research agendas,

interpretations, and outcomes. Within this thesis, cultural humility functions as a decolonising orientation: it requires attentiveness to power, accountability to participants, and reflexive awareness of how research systems can reproduce epistemic injustice. By situating cultural humility within decolonial ethics, I position ROSHNI-2 not only as an inclusive intervention model but as part of a broader intellectual project to redistribute power, restore voice, and legitimise the knowledge of BSA women.

5.4.3 Positionality, Reflexivity and Relational Knowledge

My own identity has been central to how I understand this work. As a British-born Indian Muslim woman and the eldest of five children in a South Asian family, I have long navigated the intersections of culture, faith, gender, and expectation. These experiences have shaped how I listen, how I interpret distress, and how I understand the silences that often surround maternal mental health. They have also made visible the limitations of current policies and service pathways that fail to meaningfully engage the communities they are meant to serve. Despite national commitments to equity and inclusion, tokenistic involvement often persists.

Communities are often described as “hard to reach”, a phrase I absorbed early in my career. But during the setup of ROSHNI-2, a community leader in Leicester challenged me gently: “Are we hard to reach? You walked through the door easily. We are not hard to reach; you are trained to work in certain ways. That makes us easy to ignore.” That moment changed the language I use and the assumptions I hold. It taught me that inclusion is not about offering a seat at the table; it is about co-producing the table itself.

This shift in thinking has shaped my approach to research governance, recruitment, and intervention delivery. Cultural humility has guided me to interrogate power dynamics, reflect on my positionality, and advocate for more inclusive systems. It has also shaped how I understand therapeutic outcomes. In mainstream services, success is often defined by attendance, completion, or symptom reduction. But for many British South Asian women, especially those navigating stigma, language barriers, and generational silence, simply attending therapy and beginning to name their distress is a meaningful outcome.

In the PHP sessions, we intentionally opened early sessions with culturally relevant case studies that reflected familiar dynamics: tensions with in-laws, fear of judgement, exhaustion that could not be voiced. Women often paused and said, “That sounds like me.” These moments of recognition were powerful. They helped dismantle stigma and allowed women to begin sharing their own stories, often for the first time. A key lesson I have learned through this work is that stigma holds power only when people are left without the language or knowledge to make sense of their experiences. When we educate in culturally meaningful ways, stigma loses its power.

5.4.4 Epistemic Justice and the Restoration of Voice

A central contribution of this thesis is the reframing of community engagement from a recruitment strategy to a matter of epistemic justice (Fricker, 2007). Historically, the label “hard to reach” has functioned as a form of testimonial injustice, where the lived experiences of British South Asian women were undervalued or excluded from the evidence base. In reflecting on my paper ***Khan et al. (2019)*** and the subsequent ROSHNI trials, I argue that my role was not simply to “reach” these women, but to support their ability to speak for themselves.

Through co-production and culturally humble engagement, they became active contributors to the work rather than passive participants. This aligns with decolonial scholarship (Bhakuni & Abimbola, 2021), which emphasises the legitimacy of community-held knowledge and challenges the dominance of Western epistemologies. The success of the ROSHNI model therefore lies not only in its recruitment outcomes but in its capacity to restore the voices of marginalised women and reposition their knowledge as central to intervention design, delivery, and evaluation.

5.5 Next steps – ROSHNI3

The next phase of this programme is ROSHNI-3, a programme-grant bid I am now leading as joint lead applicant. While ROSHNI-2 showed that culturally adapted, group-based interventions can improve access and early outcomes for BSA women, the key question now is how such approaches can be sustained, scaled, and embedded into routine care. ROSHNI-2 findings ***(Husain, Lunat et al., 2024; Husain***

et al., 2025) demonstrated significant clinical improvements at four months, but the between-group difference diminished by twelve months as the control group "caught up", suggesting a lack of ongoing, culturally responsive support within routine services. PHP works effectively as an early, intensive intervention, but long-term recovery requires pathways that extend beyond the initial 12-session group, consistent with evidence that perinatal depression in minoritised groups is shaped by chronic structural stressors (Edge, 2010; Prady et al., 2016). ROSHNI-3 will therefore examine stepped-care or community-embedded follow-on models to maintain gains and support sustained wellbeing.

The proposed study will explore scalable delivery through digital pathways, family-inclusive approaches, and community-embedded engagement strategies. A core component will be lived-experience leadership throughout, with an expanded focus on fathers and wider family members, recognising the collectivist contexts that shape maternal wellbeing. To prepare for this, in 2025 I conducted PPIE and community consultations to shape the proposal from its earliest stages. Fig. 2 captures key priorities from these discussions.

Figure 4 – Feedback from ROSHNI-3 community consultations

5.6 Research leadership – role as co-applicant

My role as a co-applicant on a new funded £11 million, mental health research initiative led by Lancaster University (https://www.lscft.nhs.uk/news/lancashire-and-south-cumbria-host-new-gbp11m-mental-health-research-group) extends the application of ROSHNI-2 learning far beyond publications. As a member of the group leading the *Voices with Impact* workstream on this project, I draw directly on the principles of cultural humility and the global learning that shaped the ROSHNI trials to ensure that lived experience is embedded from the earliest stages of research design. This workstream is responsible for building structures where community expertise is not an add-on but a central organising principle., I will help shape national research infrastructures so community voices guide priorities, governance, and implementation. It enables the lessons of ROSHNI, shared ownership, reflexivity, relational ethics, and epistemic justice, to influence future mental health research. This continues my commitment to moving from extractive research cultures to collaborative ones grounded in lived experience and cultural humility.

I am also a co-applicant on CaPE (NIHR209260), an NIHR fundednational trial developing culturally adapted psychoeducation for African and Caribbean people with bipolar disorder, reflecting my expertise in culturally competent research delivery. This will include co-design with community leaders, faith groups, and lived experience advisors to ensure the intervention is meaningful and acceptable.

5.7 Contribution to policy

My growing contribution to national policy is reflected in my recent appointment in 2026 to the Health Equity Expert Reference Group of the new National Maternity and Neonatal Taskforce, established by the Secretary of State for Health and Social Care in 2025[12]. The Taskforce will develop the national action plan responding to the National Maternity and Neonatal Investigation, a national programme in England that investigates serious safety incidents in maternity and newborn care to improve learning across the NHS. Part of my role will be to hold the system to account for delivering improvements in outcomes and experiences for women and babies. Within this reference group, I bring learning from the ROSHNI trials, and my work with

[12] https://www.gov.uk/government/news/national-maternity-investigation-launched-to-drive-improvements

underserved communities to ensure that cultural humility, lived experience, and equity remain central to national decision making.

Looking ahead, several areas require further attention. Paternal mental health remains underexplored, despite growing evidence that fathers also experience distress during the perinatal period. Interpersonal violence, particularly in the context of cultural stigma, requires culturally grounded, trauma-informed interventions. In addition, infertility, an area I understand personally as an individual with lived experience of 8 years, remains a silent source of suffering for many women, with limited culturally appropriate support. I aim to extend the ROSHNI model to these areas, ensuring that women and families across the life course are not left behind.

I remain committed to bridging the gap between research and reality, between evidence and equity. High-quality research, when grounded in lived experience and community wisdom, can change not only policy and practice but also lives. The women and families who trusted me with their stories remain at the heart of this work. Their voices remind me why cultural humility matters: because listening, with compassion and curiosity, is where real transformation begins.

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ROSHNI-2 Impact and Outputs Report

1. Study Overview

Title: ROSHNI-2: Multi-Centre Randomised Controlled Trial (RCT) of a Group Psychological Intervention for Postnatal Depression in British Mothers of South Asian Origin
Duration: 2017–2022 – Dissemination activities 2022-2026

Sponsor: Lancashire and South Cumbria NHS Foundation Trust (LSCft)
Funder: National Institute for Health Research – Health Technology Assessment (NIHR-HTA) (14/68/08)
Meaning of ROSHNI: "Light" in Urdu/Hindi, symbolising hope, and recovery

2. Key Outputs in media, policy and national events.

1. *The Lancet* In Conversation with podcast 12 November, 2024: https://www.thelancet.com/multimedia/podcasts/in-conversation-with/lancet
2. 'South Asian Heritage Month: Farah's research passion for delivering culturally tailored care for new mums with postnatal depression' 7 Aug 2025: https://www.lscft.nhs.uk/news/south-asian-heritage-month-farahs-research-passion-delivering-culturally-tailored-care-new-mums-postnatal-depression
3. Dean's Grand Rounds: Health inequalities in global perinatal mental health, evidence and steps forward, 27 Feb 2025: https://www.rcpsych.ac.uk/events/free-webinars/free-webinars-for-members/2025/dean's-grand-rounds--health-inequalities-in-global-perinatal-mental-health--evidence-and-steps-forward
4. 'Groundbreaking study aims to reduce health inequalities', Lancashire Telegraph, 9 Aug 2025: https://www.lancashiretelegraph.co.uk/news/25373848.groundbreaking-study-aims-reduce-health-inequalities/
5. 'Lancet highlights important British South Asian study,' Radio Lancashire, 9 Aug 2025: https://www.bbc.co.uk/programmes/p0lw2bgw
6. Presentation East of England Mental Health learning session – uploaded to NHS Futures as a training tool: https://future.nhs.uk/EoEMentalHealth/viewdocument?docid=174822949&done=DOCCreated1&fid=45297808
7. NIHR From Global to Local: Enhancing the UK Healthcare System with Lessons from CEI in LMICs webinar, 10 Feb 2026: https://www.youtube.com/watch?v=1WO7cK3xbRw

3. Impact

- **Clinical Impact:**
  Improved access to culturally sensitive mental health support for BSA mothers. Enhanced understanding of postnatal depression in underserved communities.
- **Service Impact:**
  Staff training on cultural competence and inclusive mental health practices. Ongoing discussions with services on PHP integration into service pathways.

- **Policy & Practice:**
  Evidence contributed to national conversations on equity in maternal mental health care. Informed NIHR and NHS strategies on inclusive research and service delivery

Evidence from the Overton policy-tracking report included shows that ROSHNI research has informed national and international policy discussions on perinatal mental health, ethnic inequalities, and culturally adapted psychological interventions. Since 2022, ROSHNI publications have been cited in eight policy documents across three countries (UK, Sweden and France) including UK Government bodies, NHS-related agencies, Perinatal Mental Health Assessments Bill (https://bills.parliament.uk/bills/4029), and a UK Parliament Select Committee (https://committees.parliament.uk/writtenevidence/93629/html/). This demonstrates clear reach across the public sector and legislative landscape.

The influence of ROSHNI has contributed to several observable changes:

1. Greater policy recognition of ethnic inequalities in perinatal mental health

ROSHNI evidence has been used in policy documents addressing unequal access to perinatal mental health services for ethnic minority women. This has helped shift national policy language from “hard to reach” to structural barriers and service inaccessibility, supporting a more equitable framing of maternal mental health.

2. Adoption of culturally-adapted CBT approaches in policy and guidance

Four policy citations appear in clinical guidance documents, indicating that ROSHNI findings have shaped recommendations on:

- culturally adapted CBT
- inclusive research practice
- community-engaged recruitment models

This has influenced how services design and deliver psychological interventions for minority groups.

3. Influence on commissioning and service planning

The ROSHNI economic evaluation ***(Ullah, Lunat et al., 2025)*** has been cited in policy papers relating to NHS commissioning and resource allocation, demonstrating that culturally adapted interventions can be highly cost-effective. This evidence is being used to support commissioning decisions within Integrated Care Systems.

4. International relevance and transferability

Citations from Sweden and France show that ROSHNI is informing European policy discussions on migrant maternal mental health and culturally adapted care. This demonstrates international benefit and transferability of the model.

5. Alignment with global priorities

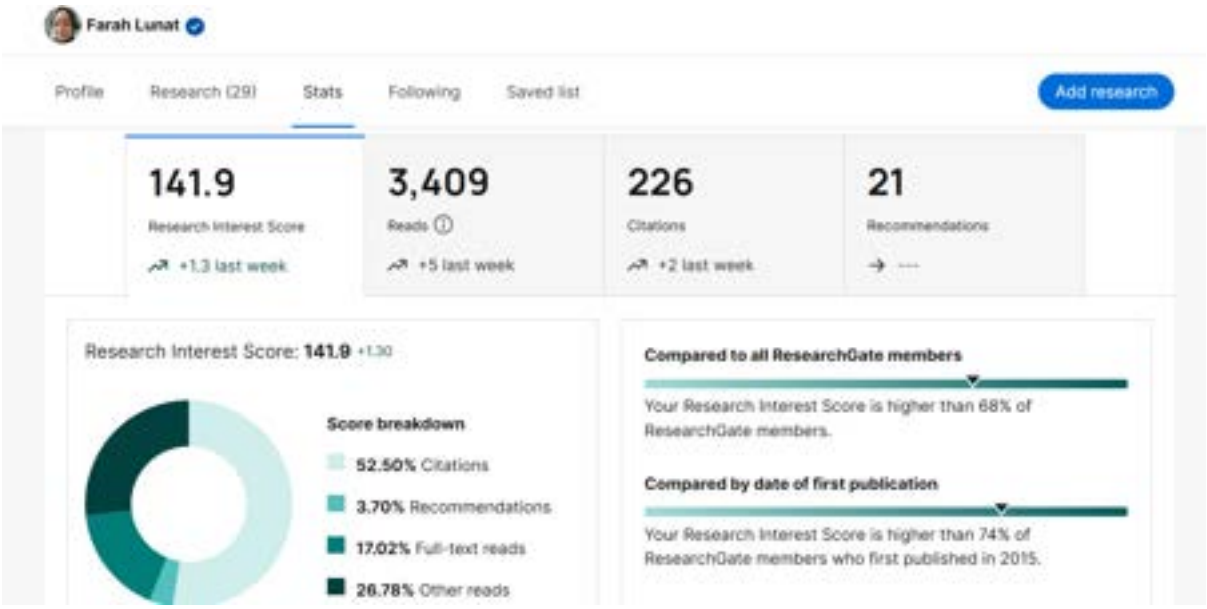
ROSHNI’s policy influence aligns with:

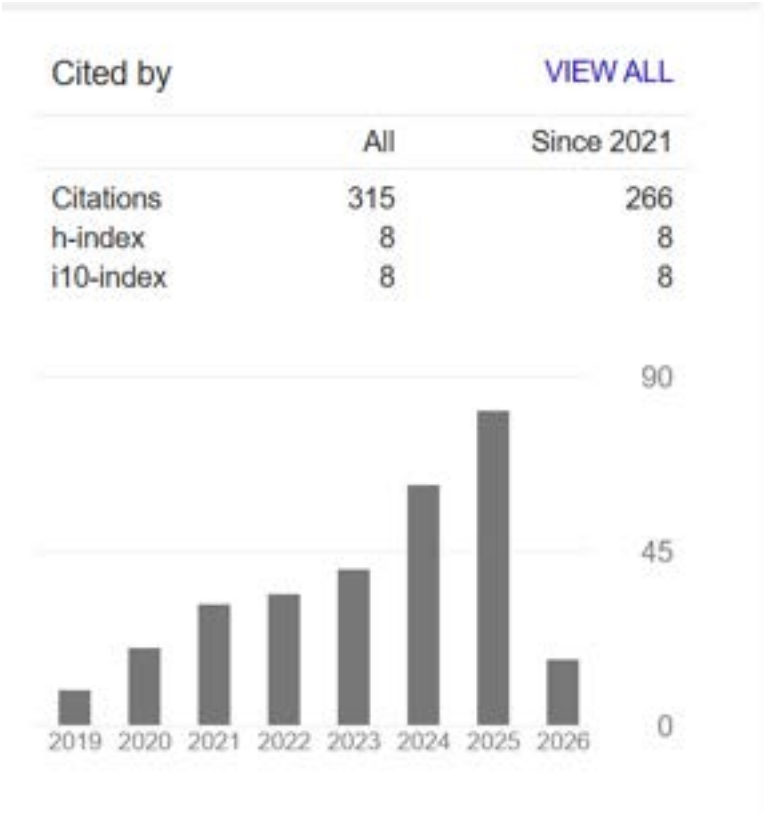
- SDG 3: Good Health and Well-being (9 documents)
- SDG 10: Reduced Inequalities (4 documents)

- SDG 5: Gender Equality (1 document)

This evidences the programme’s contribution to global health equity.

- **Research Legacy:**
  Foundation for future studies on culturally adapted interventions
  Strengthened capacity for inclusive research within Lancashire and South Cumbria NHS Foundation Trust.





Together, these metrics illustrate the growing academic and public reach of the ROSHNI research portfolio. My ResearchGate profile shows sustained engagement, with over 3,400 reads, 226 citations, and a Research Interest Score higher than 68% of all members, reflecting strong interest from researchers, clinicians, and practitioners. The Google Scholar citation trajectory demonstrates a clear upward trend, with citations increasing year-on-year since 2019 and accelerating sharply from 2023 onwards, coinciding with the publication of ROSHNI-D, the ROSHNI-2 protocol, and the Lancet trial results. This pattern evidences the widening influence of the programme across maternal mental health, cultural adaptation, and health inequalities research. When viewed alongside the Overton policy-tracking analysis, these academic metrics reinforce the broader impact of the ROSHNI model across research, policy, and practice, demonstrating both reach and sustained benefit to the field.

Consultation events to form next steps: July 2025

14th and 16th July: Consultation events for mums, dads, and wider family members.

We're inviting you to a consultation session to help shape a new research project:
ROSHNI3 – Breaking Stigma: Addressing Postnatal Mental Health in British South Asian Families

This project builds on the success of ROSHNI2, the largest-ever study of postnatal depression among British South Asian women. Now, we want to hear from you!

What to Expect
A short presentation from the research team introducing ROSHNI3, followed by a friendly, open discussion where your feedback will help shape the project. Discussion topics include:

- **Preferred formats and barriers to digital access**
- **Cultural nuances and stigma messaging**
- **Family involvement models**
- **Why Your Voice Matters**

You don't need any research experience or to have taken part in ROSHNI2—just bring your perspective. All feedback is welcome.

This event is part of our public involvement work to ensure that the voices of British South Asian women and families are heard and embedded early in the research design.

To book please text Farah Lunat on 07790 387718 or email: farah.lunat@lscft.nhs.uk

17th July: Consultation event for stakeholders (e.g. community groups, service providers etc.)

SHARE YOUR VIEWS

Stakeholder Feedback and Consultation event

17 JULY, 1PM

Join us on online - link will be sent after registration

We're inviting you to a feedback and consultation session.
We want to feedback on the ROSHNI2 project, a chance for us to thank you for your support and share our learning and next steps.

We also want to tell you about:
ROSHNI3 – Breaking Stigma: Addressing Postnatal Mental Health in British South Asian Families

This project builds on the success of ROSHNI2, the largest-ever study of postnatal depression among British South Asian women. As organisations and community groups who work closely with our population, we want to hear from you!

What to Expect
A short presentation from the research team sharing learning from ROSHNI2 and introducing ROSHNI3 proposal, followed by a friendly, open discussion where your feedback will help shape the project.

This event is part of our public involvement work to ensure that the voices of the community are heard and embedded early in the research design and that this is carried through the project.

To book a place please text Farah Lunat on 07790 387718 or email farah.lunat@lscft.nhs.uk

ROSHNI-2

ROSHNI-2

Impact & Dissemination Plan

Chief Investigator: Professor Nusrat Husain
Project Locations: North West, London, Yorkshire, Midlands

ROSHNI-2

NHS
National Institute for Health Research

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ROSHNI-2

Multi Centre RCT of a group psychological intervention for Postnatal depression in British mothers of south Asian Origin

Key Messages

(1) The rates of perinatal depression in British South Asian women are high

(2) Perinatal depression (PND) is known to cause disability and suffering in women and negative consequences for their infants and their family.

(3) Due to linguistic and cultural barriers, South Asian women do not access health care services. This has been highlighted as a major contributor to ethnic inequalities in access to appropriate mental healthcare.

(4) Mothers from South-Asian backgrounds (Bangladesh, Pakistan, Sri Lanka and India) make up for a very large number of births in the centres participating in this study.

(5) There is a growing concern about ethnic disparities in the provision and access to PND services which is an identified priority in UK.

The Project

ROSHNI-2: Multi-Centre RCT of a group psychological intervention for postnatal depression in British mothers of South Asian origin. The research project has been funded by the National Institute for Health Research (NIHR-HTA) and Lancashire Care NHS trust is the sponsor for this study.

Objectives

The primary objective of the project is to evaluate the clinical and cost effectiveness of a culturally adapted group psychological intervention (Positive Health Programme, PHP) in primary care for British South Asian (BSA) women with postnatal depression compared with treatment as usual (TAU)

• The secondary objective of the study is to evaluate the impact of the intervention on secondary outcomes (health status and quality adjusted life years, parenting competence, social function, anxiety, satisfaction with care) compared to treatment as usual.

Update

The study recruitment ended in March 2020. The study exceeded its recruitment target and has randomised 733 participants in total across the study.

Dissemination and Engagement plan

We have developed our impact plans through consultation with all relevant stakeholders and target audiences and we will hold further consultations to develop an impact and dissemination strategy in these final 6 months. The study has been widely promoted and the study findings will be disseminated in partnership with the service users and carers.

The ROSHNI2 trial is now being recognised for the way in which team members, service-user and professional stakeholders have conscientiously adapted to change and maximised the scope of opportunity. The progress in cultural engagement through this trial has been recognised through social media campaigns, IAPT BAME positive practice guide, invitations to speak on cultural engagement for maternal mental health day and other avenues. We have made every effort to address many barriers to recruitment to research within the British South Asian community by tailoring our recruitment methodology and engagement activities. We hope this knowledge exchange of our lessons learnt will have an impact on future work in this area that will be applicable not just within maternal health but also wider engagement of this hard-to-reach community to other valuable research work.

As detailed in our original impact, output and dissemination plan of our application we have recorded shows for TV, radio and disseminated videos on social media to promote the study, increase education and awareness of maternal mental health and ensured all work is carried out in the study languages. We have worked closely with the 3rd sector and charities such as MIND, Ethnic Health Forum, Sangat foundation and others to raise awareness and will include them in our dissemination activities. Furthermore, the results of the study will be written up for academic publications in both peer reviewed and non-peer reviewed journals such as the British Journal of Psychiatry, The Lancet and Psychological medicine, and presented in national and international conferences, and further disseminated to interested local and national groups. We have published a report detailing some of our ways of working with this group and we are working on a lessons learnt paper to document all strategies utilised in enhancing engagement, recruitment and retention activities when working with British South Asian women.

We have extensive experience in promoting our research within the BSA community including social media, radio, television and community seminars and would seek to replicate these strategies for our research impact activities. Disseminating the findings will help to facilitate awareness about maternal mental health and its treatment in the BSA community. Information will be collated to provide an educational tool for maternity healthcare professions, community sector organisations, better births teams and any other relevant disciplines. This will in turn promote cultural understanding, sensitivity and raise awareness of the identification and treatment of mental health difficulties.

Impact on Policy: We also propose to conduct a round of consultations with NHS stakeholders and with key local, regional, and national policy makers to inform policies around engagement with the BSA community. These consultations will include service users from these communities as well as key decision makers. **Training package:** The qualitative research will identify difficulties and barriers in engaging with this population, thus informing the refinement of the training package. We are developing the existing curriculum to train multi-disciplinary staff in the engagement of the BSA population. Impact on service users: The project will aim to improve the mental health outcomes of BSA individuals experiencing mental health difficulties by enhancing engagement with services, trust in services and raising awareness and education through tackling stigma.

Outcomes/deliverables from the project	Timescale to benefit	Impact
Dedicated study website – developed for promotion of study – www.roshni2.com Aim to apply to NHS England for the development of the website as an education resource to host the training toolkit, research outputs and knowledge exchange	0 – 60 months	A public platform for findings to be disseminated nationally to commissioners, mental health teams, specialist perinatal mental health services, midwifery and health visiting services, community sectors, patients and carers and charity organisations.
Hosting a national conference/mental health festival To share research findings and recommendations whilst also bringing together all involved in transforming care, including service users, families and care providers, advocates, community teams, social workers, commissioners and other stakeholder groups, to share good practice and improve service provision.	55-60 months	Influence the way the maternity pathway engages with ethnic minority communities and develop a more culturally aware and informed workforce. Improving the wellbeing of service users and sustainability of culturally sensitive interventions
Teaching and Training Develop a low cost training toolkit for staff teams, care providers, NHS teams and 3rd sector and voluntary sector teams based on the findings from the research. Educational interventions are one of the more effective ways of making change happen.	55-60 months	Embed findings in practice, improving the experience of South Asian women experiencing mental health difficulties. Training to contribute to the development of a culturally sensitive maternity workforce
Recommendations Dissemination of recommendations through charities who often have powerful networks such as MIND	55-60 months	Increase the visibility of our recommendations to the Maternal Mental Health community nationally and internationally.
Dissemination of findings Through peer reviewed journals such as the British Journal of Psychiatry, the Lancet, Psychological medicine.	50 months onwards	This will ensure the credibility of the work and its international reach.

Influencing national guidelines and standards

Our current relationships with NHS England and working with the NHS England BAME taskforce established as part of the COVID response will support these discussion. Our contribution at this level will help to influence how the Care Quality Commission sets its quality standards for working with South Asian women experiencing mental health difficulties in the perinatal period.

What are the possible barriers for further research, development, adoption and implementation?
The implementation of our recommendations may require significant changes to the culture and working practices of some organisations. The lack of training and investment in maternity services may present a barrier. We hope to offset this barrier by providing our own training resources at low cost. We will work with the 3rd sector to provide training at minimal costs.

ROSHNI-2 Impact

2012-2016

Capacity and capability building in cultural psychiatry research is very important to us and we are optimistic that by the end of the ROSHNI-2 trial we would have identified many emerging academic stars of tomorrow. We understand that staff turnaround may be a challenge across the study period and as such we continue to train Service User Representatives to support in recruitment and engagement of the target population.

Students interested in research were given an opportunity to get involved in the project and gain valuable and insightful research experience. We supported this by hosting a volunteer and intern afternoon at the Mount which provided encouragement and training for early career researchers. We also hosted a ROSHNI2 open day at the Mount for health professionals to familiarise themselves with the research project and develop partnerships.

London Roshni 2 Launch Eastham Library: ROSHNI-2 is not just another group CBT trial for PND it is also about setting up a platform and infrastructure working with the local community for future ethnic minority research as you could see the excellent response we got from across NHS and third sector organisation at the London launch

We regularly hold career development mornings for our team members, where we focus on developing our skills and increasing our experiences within the field, so that we can better perform in our roles. We are proud to have 4 research assistants on our team, who are also official mental health first aiders.

ROSHNI-2 Stalls

We have held informational stalls at professional events, community events, health fayres and school events to raise awareness and promote the study

- Conference in London with health professionals from across Europe

- Glasgow community event to promote ROSHNI2 and raise awareness of maternal health and well-being

- Charity event

- Presentation at St James Primary School parents evening

- Blackburn community event for family health

- Suicide & Self-harm prevention event

We also take advantage of attending local community health events and setting up stalls often to promote the study and use this as another learning and community engagement activity.

To promote our Roshni-2 research project and to mark Global Women's Maternal Mental Health week 2018 we held a conference in London at the PDC centre. We were delighted to have Dr Sam Everington as our Guest Speaker.

- Global Women's Health seminar – held at University of Manchester to mark Maternal Mental Health day – presentations on ROSHNI2 were given by our CI Prof Husain and PI Professor Shanaya Rathod

- Health Fayre event

- Press for Progress Event

- Leyton Carnival

CHAI
with ROSHNI-2

We held a brunch event at a local children's centre in Blackburn to increase awareness of the study and encourage women to engage with the study team. A total of 19 women attended and 2 health visitors also joined us for this. The event was received very favourably, and we had fantastic feedback. We are hoping to do more of these across all study centres.

The clip shows coverage of the launch in London with comments from the local councillor, community workers, local PI Dr Ilyas Mirza, study CI Prof Husain and the study deputy trial managers

Following on from the Success of our Brunch events we decided to invest more of our efforts in being innovative in our approach and putting together community events. Therefore, we launched Chai with Roshni-2. We have so far had many Chai with Roshni-2 events across the Northwest, Yorkshire, Glasgow, Midlands and London. The Chai with Roshni-2 events have been successful in helping us reach out to the South Asian communities as well as raise awareness on Maternal Mental Health.

- Chai with ROSHNI-2 (London) with Madame cllr

- Chai with ROSHNI-2 with Mayor (Leicester)

- Chai with ROSHNI-2 (Burnley)

- Offical poster for event promotion

PHP AWARD CEREMONIES

For our mums we also hold Award Ceremony once they have completed the Positive Health Programme. We understand how important it is for mums to be recognised for their achievements. We give recognition to our mums by awarding them with a certificate and a celebratory meal. The ceremony also is another opportunity for us to receive feedback from mums on how we are doing and what more can be done in terms of research.

- ROSHNI-2 team members Farah, Mariya, Saadia, Afsana, Nafeesa, Tayyibah, Jyothi, Nosheen, Sadia, Zehra, Sabia, Jules pictured during PHP award celebrations in Lancashire, Bolton, Manchester & London

Let's Eat!

Food is an important part of any celebration in all cultures and we love how just by having the right venue and menu, communities can be brought closer together!

We've been fortunate to have been supported by many local businesses with our PHP celebration session.

We've engaged and maintained relationships with local businesses across our project locations, such as - Deli Delight, Querky Cafe, Salamis Restaurant, Chaiiwala.

Events

International Women's Day

To celebrate International Women's Day- Our team collaborated with InterMadrasssah to put a Chai & Crafts event for our mums and the local South Asian community. The team understands that having a cuppa along with arts and crafts can be used as an effective tool to help one destress and relax. We were also very pleased to receive feedback from many women that attended.

Offical poster used for promotion of the event

Those attending took part in various crafts activities, including creating art pieces to represent how they felt, along with sharing a reflection piece on their experiences

ROSHNI-2 team pictured at the International Women's Day event

Group of attendees pictured during the International Women's Day event

The team in London had a joint International Women's Day event with Forest Women's group in East London. They also held an event with Kiran Project to raise further awareness of the day.

Maternal Mental Health Awareness Week

This year the Lancashire ROSHNI2 team from Lancashire Care NHS Foundation Trust (LCFT) held a community event at Audley Sports Centre in Blackburn to mark World Maternal Mental Health Day. The event was supported by local organisations such as Lancashire BME network, IMO, Lancashire Women, Lancashire Mind, Action on Postpartum Psychosis, Snowdrop Doula, HomeStart Genetics, Bumps and Babies group. The event was further supported by local business such as ESKAY Apothecary, Fatima Shikora, Tessa Clemson yoga, Finch Bakery, Nafees Bakery, Blackburn Rovers, Burnley FC, RnR salon, Beesweet bookings, Rice & Curry, Amethyst & Lotus, CLOAK – who were present on the day and also kindly contributed towards the raffle which raised money for Burnley Neonatal Intensive Care Unit.

- Official poster used for event promotion

ROSHNI2 celebrates World Maternal Mental Health Day

The ROSHNI2 team from Lancashire Care NHS Foundation Trust (LCFT) hosted a community event to mark World Maternal Mental Health Day.

- A local newspaper article covered the communtiy event

- Farah Lunat speaking on the importance of tackling myths

- Anaharul educating the community on men's mental health

- Live mum and baby yoga session facilitated by Tess Clemson Yoga Studio

Attendees had the chance to write their words of wisdom for other mothers. An act that allowed those attending to bond on a deeper level.

ROSHNI team members from the Lancashire site pictured during the event

The event was a huge success in engaging with the local community, as well as building on relationships with other health organisations and businesses

We were overwhelmed by the lovely donations received from local businesses & health organisations. All raffle prizes proceeds were donated to Burnley NICU.

Additional Events

- Chai with ROSHNI2 – Dewsbury and Batley
- Drop in with ROSHNI2 – Dewsbury and Batley
- Keighley Launch – Sangat Centre
- Keighley Drop in – Bangladeshi Community Association
- Blackburn College event – Volunteers open day
- Bradford Launch – Children's Centre
- Blackburn Health Fair – Tauheedul High School
- Pendle View Radio Station – promotion.
- Coffee morning – The DEEN Centre
- Presentation @ PEEF (community organisation) – Brierfield

Screening Drop-in sessions, in partnership with local Children Centres

ROSHNI-2 Drop in - Little Harwood Children's Centre
ROSHNI-2 Drop in - Wensley Fold Children's Centre
ROSHNI-2 Drop in - Auldey & Queens Park Children's Centre

- Official poster used for drop-in promotion

- Anisha, Nafeesa, Farah & Mariya pictured at Wensley Fold

- Table set up for drop-in sessions

Media Gallery

We've been fortunate to be able to showcase our passion and progression with the project by attending various media events and taking part in radio & televised interviews.

ROSHNI-2 on BBC Asian Network radio

WFWN -Get inspired & Inspire Others radio

ROSHNI-2 appearance on Islam Channel

Maternity Voices Partnership Chairs

Roshni2- Pregnancy, baby and toddler event

A conversation with Wajeeha Ameen

Chief Investigator Professor Nusrat Hussain on Dunya TV - A conversation with Wajeeha Ameen

Research Manager Farah Lunat on Dunya TV - A conversation with Wajeeha Ameen

News

British South Asian mums needed for health study

By Harriet Whitehead | @Harriet_LT
Reporter

3 comments

BRITISH South Asian mums with children under 12 months are being invited to participate in a research study that looks at the rise in postnatal low mood and stress among South Asian women.

The four-year ROSHNI-2 study is being led nationally by Lancashire Care NHS Foundation Trust's Professor Nusrat Husain.

Up to £8.1 billion is estimated to be spent each year on perinatal mental health problems in the UK.

Professor Husain said "The rates of postnatal low mood in the majority UK population are 10 to 15 percent and in British South Asian women (Pakistan, India and Bangladesh) the rates are reported to be higher.

"This project seeks to determine how clinically effective and cost-effective the culturally adapted group positive health programme is for British South Asian women with low mood after child birth compared with routine treatment."

For further details contact Farah Lunat on farah.lunat@lancashirecare.nhs.uk or Nafeesa Bhatti on nafeesa.bhatti@lancashirecare.nhs.uk on 01254 612508 and 07507844725.

Lancashire Telegraph article detailing project details

Call for British South Asian mothers for study on postnatal low mood

British South Asian mothers with children under 12 months are being called on to participate in a research study that looks at the rise in postnatal low mood and stress among South Asian women.

By The Newsroom

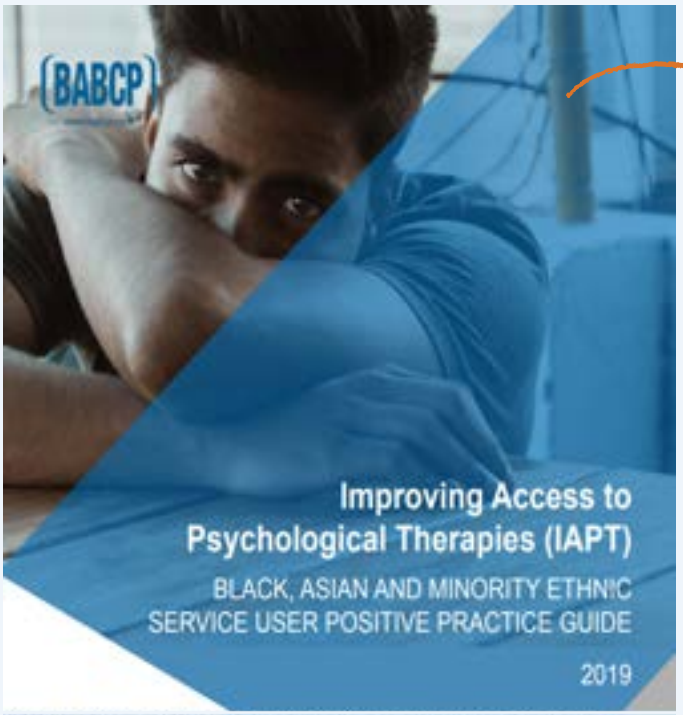
Professor Nusrat Husain

The study, entitled ROSHNI-2, is running for four years and is the largest of its kind to be funded by the Health Technology Assessment (HTA) programme which is run by the NHS National Institute for Health Research.

Led nationally by Lancashire Care NHS Foundation Trust's Professor Nusrat Husain, the study is researching alternative culturally adapted methods of supporting South Asian women experiencing low mood and stress following childbirth.

Professor Nusrat Husain, Honorary Consultant Psychiatrist at Lancashire Care NHS Foundation Trust, said:

Lancaster Guardian article detailing project details



ROSHNI-2 Project for British South Asian Women with Postnatal Depression

In the UK, postnatal depression (PND) is more common in British South Asian women than in majority white women, suggesting that ethnic and cultural differences are risk factors for developing PND. British South Asian women have higher birth rates compared to the majority white population. Previous research indicated that British South Asian women with depression may have difficulties with marital and other close relationships, housing and finance, lack social support and the resources to obtain assistance, are isolated and lack fluency in English. Isolation and lack of social support are therefore important elements to be addressed in interventions for depression in this population.

The ROSHNI-2 (meaning light in Urdu and Hindi) study is a multi-centre randomized controlled trial with four- and 12-month follow-up. The trial has been funded by the NIHR-HTA programme.

The culturally adapted group intervention is based on the principles of CBT and was developed following qualitative interviews with British South Asian mothers about the type of help they might want to access. The central adaptations made to the intervention were: language-specific translations of CBT terms, culturally appropriate assignments and homework, folk stories and examples with consideration given to religious beliefs, and understanding the ABC model using culturally appropriate stories.

The ROSHNI-2 study focuses on improving engagement with the family, self-esteem, social support and independent coping strategies. The emphasis is on keeping the programme culturally appropriate. This includes a family-centred recruitment pathway, ensuring that all study assessments and the delivery of the programme is available in the key South Asian languages (Urdu, Bengali, Gujarati, Punjabi, Hindi and Tamil), while also using stories to help service users understand situations and apply the principles of CBT, incorporate religious/spiritual activities; further, the provision of childcare and transport is also important.

Given the concerns about blame, labelling and stigma, the women expressed a preference for the programme to be called the Positive Health Programme (PHP). A major adaptation is an engagement protocol for mothers, fathers and extended family. To address stigma concerns, it is framed as an educational programme for building problem-solving and additional life skills, and people who attend are given certificates at the end of the intervention. The PHP involves 12 weekly sessions facilitated by a trained research therapist who leads the group. Regular supervision is provided by a senior CBT therapist and a senior psychiatrist. The sessions last approximately 60-90 minutes and involve group discussions, case scenarios, individual goal-setting and skills-based activities. The programme has been designed to be simple and pragmatic and can be delivered by an individual trained in basic mental health and CBT principles.

ROSHNI2 cited as a best practice example in the BABCP IAPT positive practice guide 2019

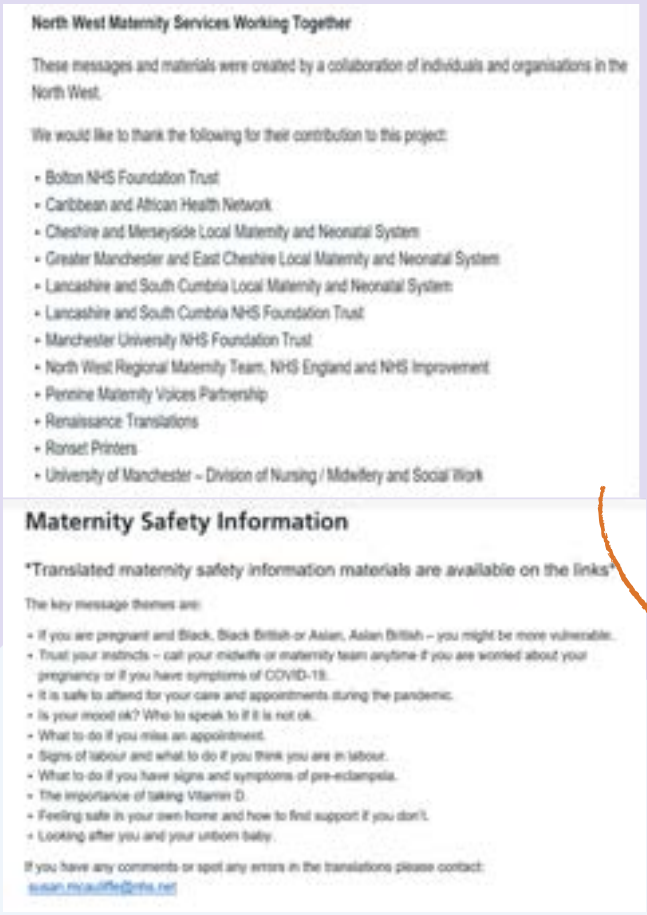
Our work has been cited as part of the IAPT BAME national guidelines launched in June 2019. The ROSHNI2 project description is included in the guide as a good practice example of adapting treatment to meet the needs of a specific population
Our deputy manager Farah Lunat is presenting this and other learning points as part of her role as leader of the IAPT Clinical Skills Forum: Perinatal Interventions.

SBK leading minds in Healthcare

National Networking Forum

Agenda

9.30	Registration and refreshments
10.00	Leader's opening remarks Farah Lunat, Deputy Project Manager, Lancashire Care NHS Foundation Trust
10.10	What is and isn't possible in an IAPT service
10.50	What do women want? Child outcomes and maternal mental health
11.30	Networking break
11.50	Insight into the ROSHNI2 project: IAPT BAME Positive Practice Guide
12.30	Networking lunch
2.00	Innovative ways of working, developing new pathways and partnerships Sarah Mullaney, Senior Psychological Wellbeing Practitioner, Kirklees & Calderdale Improving Access to Psychological Therapies Service (IAPT), South West Yorkshire Partnership NHS Foundation Trust
3.00	Networking break
3.20	Tackling anxiety and depression in the perinatal period
4.00	Close of day



North West Maternity Services Working Together

These messages and materials were created by a collaboration of individuals and organisations in the North West.

We would like to thank the following for their contribution to this project:

- Bolton NHS Foundation Trust
- Caribbean and African Health Network
- Cheshire and Merseyside Local Maternity and Neonatal System
- Greater Manchester and East Cheshire Local Maternity and Neonatal System
- Lancashire and South Cumbria Local Maternity and Neonatal System
- Lancashire and South Cumbria NHS Foundation Trust
- Manchester University NHS Foundation Trust
- North West Regional Maternity Team, NHS England and NHS Improvement
- Pennine Maternity Voices Partnership
- Renaissance Translations
- Ronset Printers
- University of Manchester – Division of Nursing / Midwifery and Social Work

Maternity Safety Information

Translated maternity safety information materials are available on the links

The key message themes are:

- If you are pregnant and Black, Black British or Asian, Asian British – you might be more vulnerable.
- Trust your instincts – call your midwife or maternity team anytime if you are worried about your pregnancy or if you have symptoms of COVID-19.
- It is safe to attend for your care and appointments during the pandemic.
- Is your mood ok? Who to speak to if it is not ok.
- What to do if you miss an appointment.
- Signs of labour and what to do if you think you are in labour.
- What to do if you have signs and symptoms of pre-eclampsia.
- The importance of taking Vitamin D.
- Feeling safe in your own home and how to find support if you don't.
- Looking after you and your unborn baby.

If you have any comments or spot any errors in the translations please contact:
susan.mcauliffe@nhs.net

North West Services

North West Maternity Services

Maternity Safety Information

English
Amharic / አማርኛ
Arabic / العربية
Bangla / বাংলা
Farsi / فارسی
French / Français
Hindi / हिंदी
Kurdish Sorani / سۆرانی
Somali
Spanish / Español
Tigrinya / ትግርኛ
Urdu / اردو
For Professionals

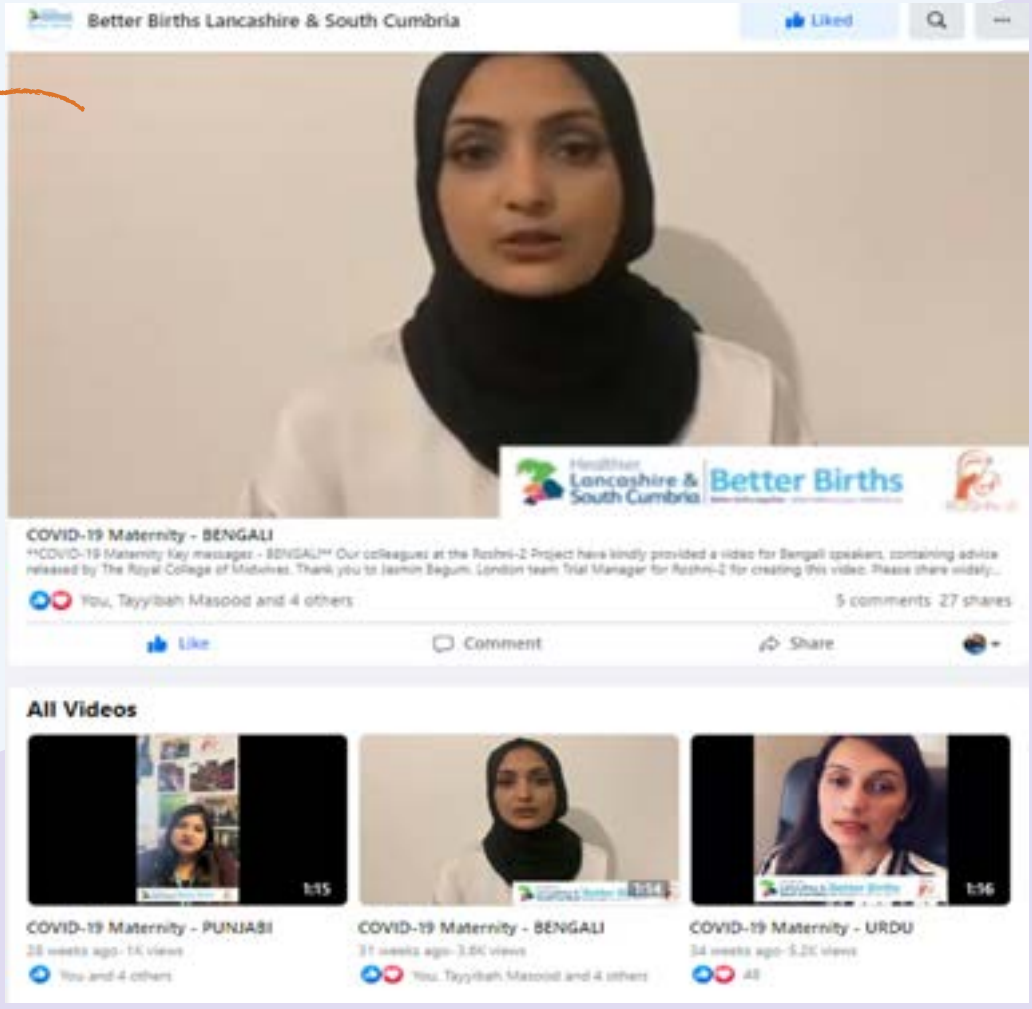
Urdu / اردو

Booklet – Maternity Safety Information

Posters – Maternity Safety Information

BAME Taskforce – COVID19 safety messages – NHS England NHS Improvement

COVID 19 maternity messages in Bengali, Urdu and Punjabi recorded by the ROSHNI2 team



Better Births Lancashire & South Cumbria

Liked

Lancashire & South Cumbria | Better Births

COVID-19 Maternity - BENGALI

You, Tayyibah Masood and 4 others

5 comments 27 shares

Like Comment Share

All Videos

COVID-19 Maternity - PUNJABI

COVID-19 Maternity - BENGALI

COVID-19 Maternity - URDU

We try to ensure we send out regular updates to community and health professionals via our website, emails and through our social media pages.

Our monthly newsletters are a great hit, not only for our ROSHNI-2 mums but also for building team rapport.

GLOBAL MENTAL HEALTH & CULTURAL PSYCHIATRY

NEWSLETTER

Issue 2. Aug 2017

Professor Nusrat Husain

Hello and welcome to the second edition of the Global Mental Health and Cultural Psychiatry newsletter. This edition will focus on Maternal Mental Health Awareness. Research over last few years has shown the importance of Maternal Mental health and the long term effects it can have on mothers, children and even fathers. A mother's health is vital, as it can shape the development of their child. We should ensure that all mother's health is taken seriously and we offer the best possible support. Happy mothers equal happy babies! Happy families! Happy societies!

Brunch with Roshni-2

The ROSHNI team organised Brunch with a group of mums who had a chance to get together and discuss their stories with one another. The brunch session was joined by a health visitor and mums were given the opportunity to ask questions. It also gave the team a chance to explain more about the ROSHNI-2 project , what it is and how they can get involved.

Global Women's Mental Health Seminar

For Maternal Mental Health week we organised a seminar at the University of Manchester, where we invited various speakers to discuss the issues at hand. It was a pleasure to have Professor Cindy-Lee Dennis from Toronto with us, a leading expert in maternal mental health. We were also joined by Professor Mukesh Kapila who delivered a talk on trauma. We would like to thank everyone who attended and all the speakers for giving us their time.

11 October 2017

www.news@jang.com

برطانیہ میں ایشیائی عورتوں کے لئے تحقیقاتی پروجیکٹ کا آغاز

ROSHNI-2

Social Media

We understand that social media may give those who ordinarily suffer in silence the freedom to share and open up about how they are feeling. Social media helps support the mental health cause by bringing a taboo topic to the forefront.

We currently have a Facebook and twitter page for the study; members of our team also use Instagram and snapchat to keep the community informed on the study and increase engagement.

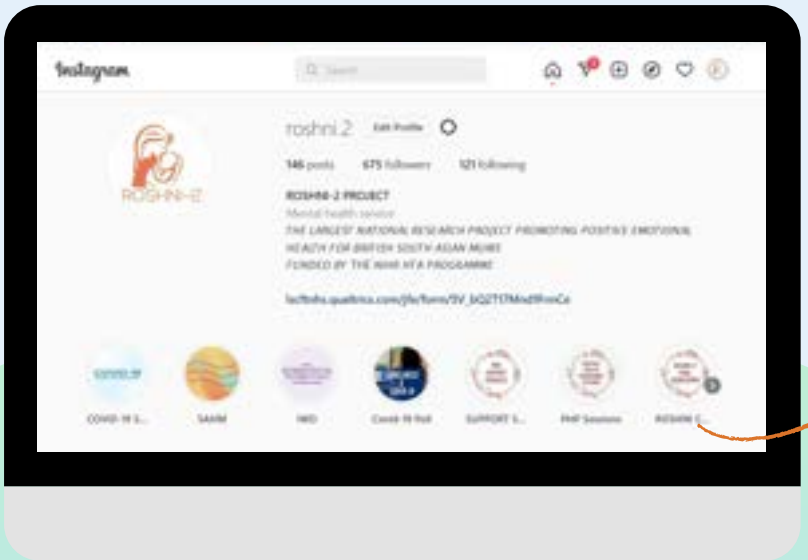
The social media and communications of the trial was managed by a service user communications consultant who has taken part in the screening and assessment phase of the study. She is currently on mat leave and this role is being undertaken now by one of our interns and supported by a service user researcher.

ROSHNI-2 Facebook Page 2017

ROSHNI-2 Facebook Page 2021

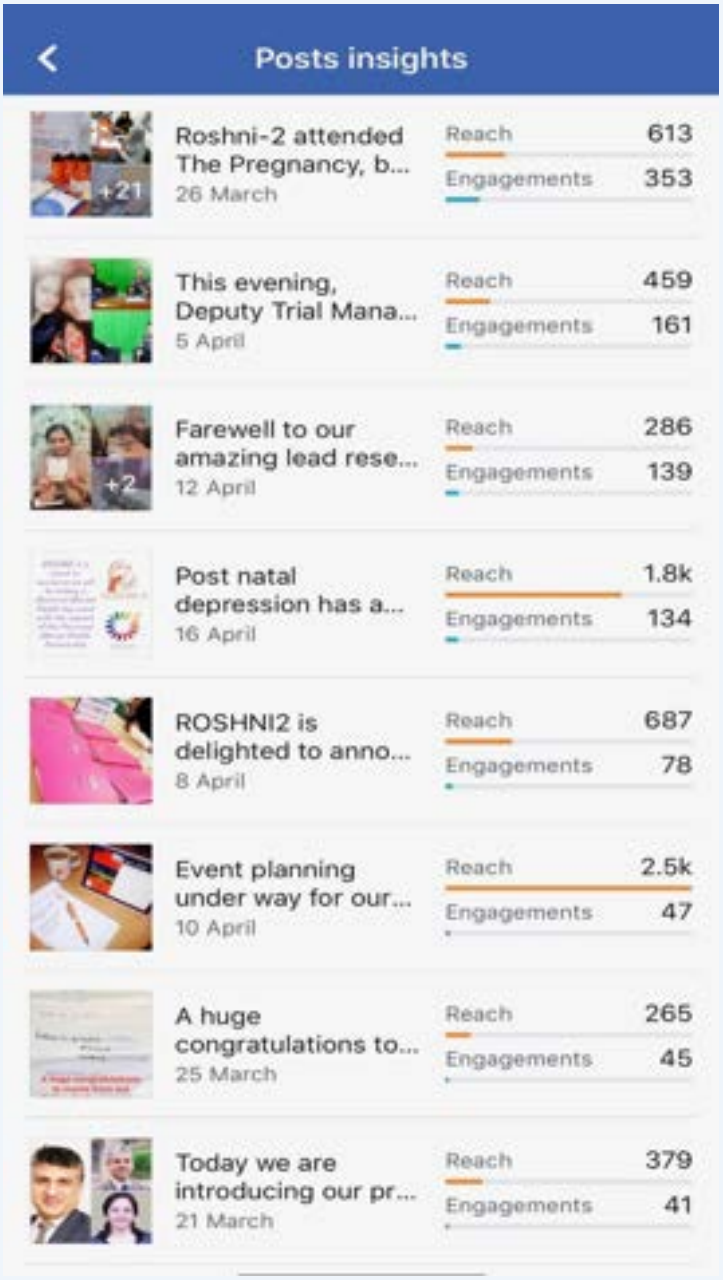
ROSHNI-2 Twitter Page 2017

ROSHNI-2 Twitter Page 2021



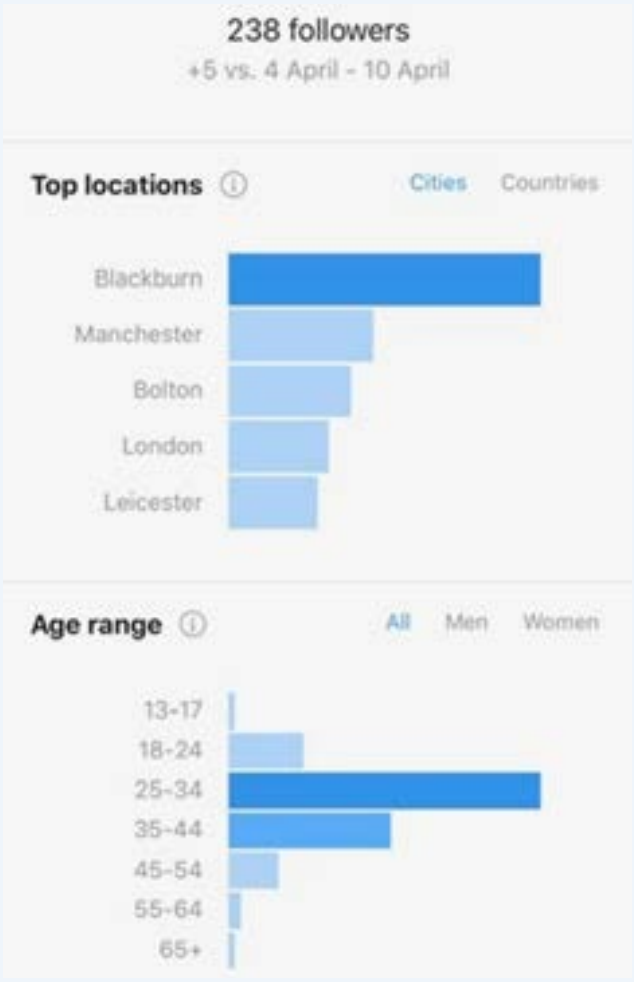
ROSHNI-2 Instagram Page 2021

Our engagement on social media has been shown to be very effective; some of our posts have been organically reaching over 1000 people and every month our number of followers on Facebook have been increasing.



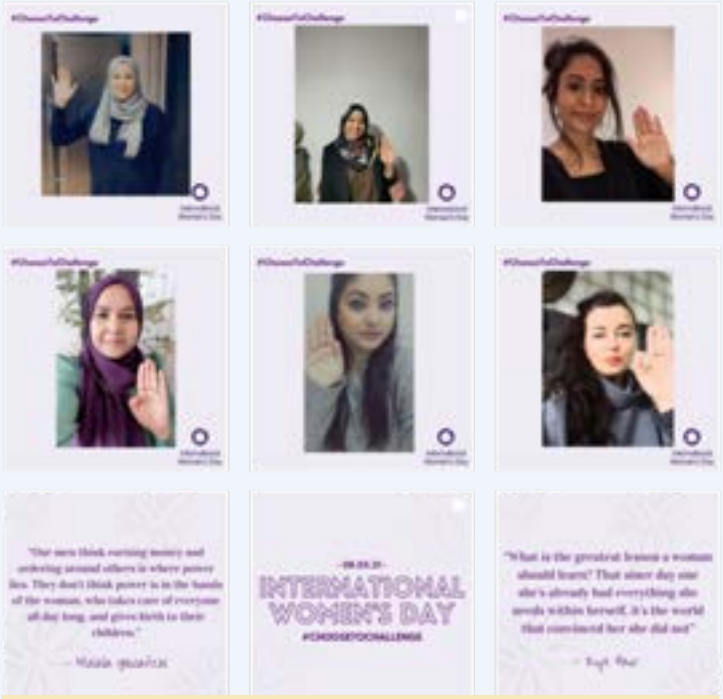
Since January we have been engaging with the community through Instagram. We have found Facebook was a great way to interact with older mums, as well as first generations mothers; however we found Instagram better for interacting with second and third generation mothers who are already quite aware of PND.

Since January our number of followers from Blackburn has increased and our majority of followers on Instagram are from Blackburn. We have also seen an increase in recruitment in the Blackburn area during this time frame. Mothers we have spoken to in clinics have mentioned they already know about the work we do through our Instagram. The number of people commenting and liking what we post is also higher on Instagram, showing individuals who interact with us on Instagram are more inclined to discuss and engage with our posts.

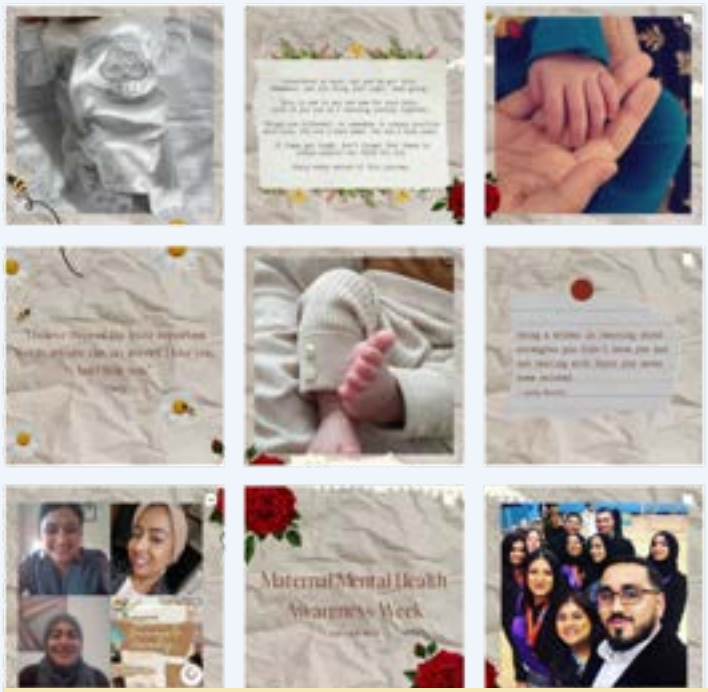


Social Media Campaigns

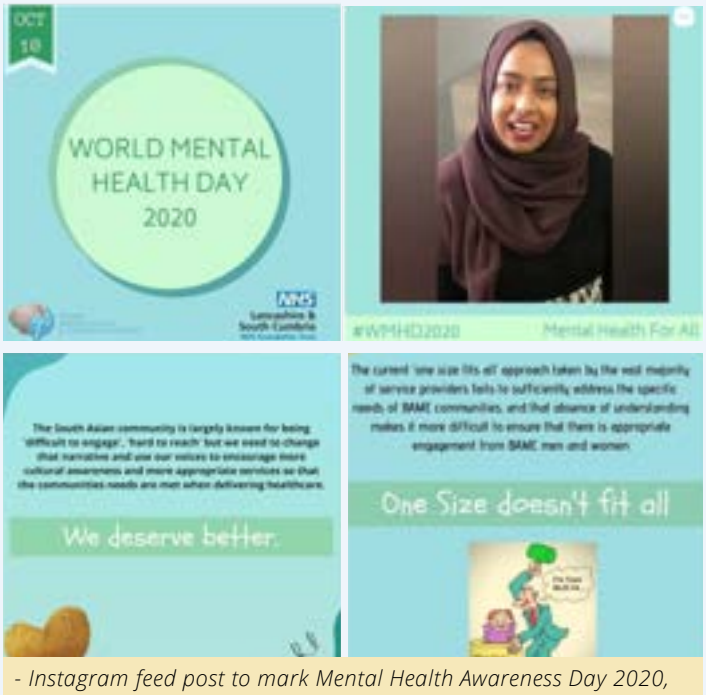
In recent years, we use our social media pages, particularly Instagram as a way of assisting in raising awareness of specific events. We found this to be particularly useful during the Covid-19 Lockdown, when in person events were not permitted. Instagram's stories function has been found useful in receiving feedback from our followers in the form of polls and feedback boxes.



- Instagram feed post to mark International Women's Day 2021



- Instagram feed post to mark Maternal Mental Health Awareness Week 2021



- Instagram feed post to mark Mental Health Awareness Day 2020, including Farah Lunat's (Research Manager) individual post to mark the day

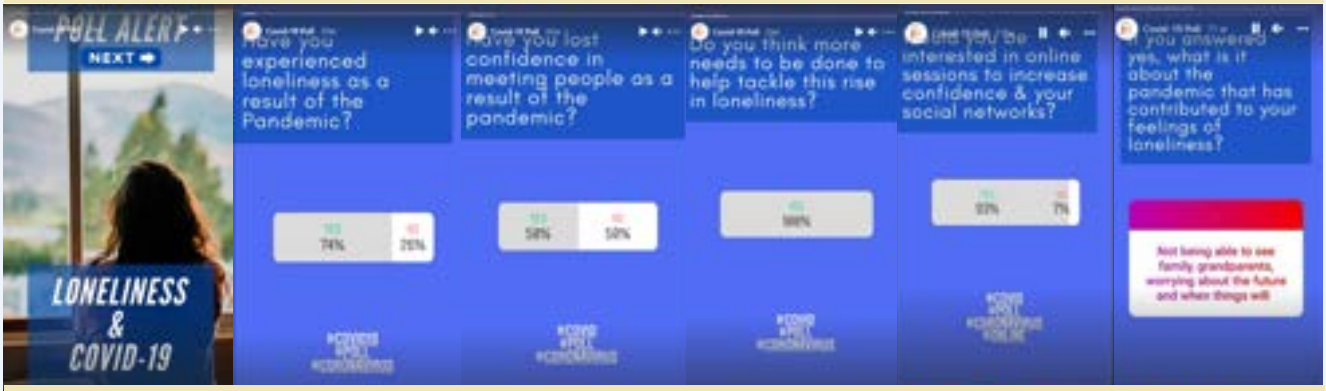
- Instagram feed post to mark Mental Health Awareness Week 2021

Instagram Stories

We have successfully been able to increase engagement and maintain relationships through using the Instagram story feature.

During awareness days/events, we typically post prompts and short quizzes to not only connect with our audience, but raise further awareness on topics relating to maternal health disparities, cultural taboos and more recently the impact of COVID-19.

- Examples of Instagram story uploads and feedback from International Women's Day 2021



- Examples of Instagram story polls upload assessing the level of loneliness felt as a result of Covid-19

- Examples of Instagram story uploads for South Asian Heritage Month 2020

ROSHNI-2

In 2022

COVID-19 ADD ON STUDY

This year, the ROSHNI-2 Project has been given the opportunity to carry out additional research with our ROSHNI Mums, looking at the wider impacts of COVID-19.

The global pandemic has caused short- and long-term consequences on many aspects of our lives. We aim to explore and understand the wider consequences of the global pandemic on British South Asian (BSA) women during the perinatal period in the context of –

- Mental Health
- Isolation
- Education
- Child Development
- Views on Vaccination
- Any other wider impacts

To ensure we had in-depth understanding of the experiences lived from those who parented through the pandemic, we held in person and online focus groups across all our recruiting sites with the hopes of gaining valuable feedback on our add on study.

In total, 25 ROSHNI-2 mums participated in our focus group

3 mums participated from Manchester

9 mums participated from London

11 mums participated from Bolton

2 mums participated from Lancashire

The discussion groups proved successful as we were able to take on many of the comments proposed by those participating, of which included –

1. Promotion of the study should be done by ringing up previous participants as it allows the mum to share her thoughts and feelings.
2. Topic of Interpersonal Violence (IPV) should only be approached when rapport has been established.
3. Researchers should define what abuse is, the different types of abuse and why it's important to speak about it.
4. To include the role of technology during lockdown and how it affected motivation, relationships, and general wellbeing.

We used ‘Qualtrics’, an online survey builder to create, manage and distribute our add on study questionnaire.

We officially went live on 11th January 2022 and have since received...

142 RESPONSES

142 RESPONSES
142 RESPONSES

Survey completion is increasing daily, and we have successfully gone from receiving an average of 5 responses a day to 12 responses.

Various methods of recruiting have been utilised when approaching potential participants, including –

·SMS Text messages
·Phone calls
·Survey Promotion via social media
·Word of mouth

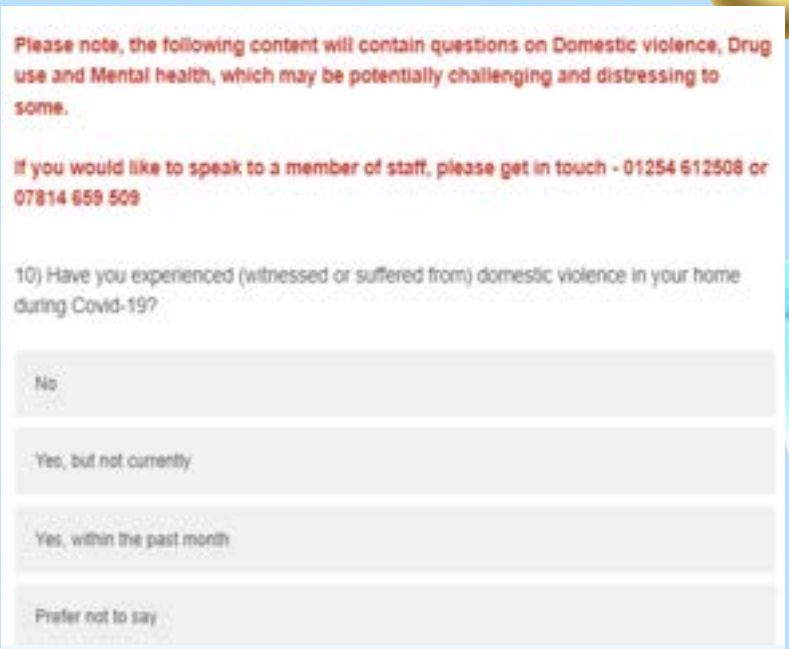
As well as an online questionnaire, we have also been conducting interviews with stakeholders, professionals, and ROSHNI-2 participants.

Stakeholder interviews have been conducted with professionals who have or currently worked with BSA women that have experienced IPV, as well as with those who understand the struggles BSA women face when accessing care for IPV

Participant interviews have been conducted with those who indicate (during the online questionnaire) having knowledge of someone going through IPV, as well as with those who have dealt or are dealing with IPV currently

Issues relating IPV increasingly worsened during the March 2020 lockdown. The nature of home confinement led to constant contact with perpetuators and victims which resulted in increased violence. In order to create prevention measures and support options, discussions around this topic with those who have an understanding are both necessary and very much needed.

- Social media call to speak with professionals who work with BSA women



- Example of IPV question found in the online survey

-Official study poster used for promotion for ROSHNI-2 add on study

- Instagram's story feature used to collect questions from the general public

- Examples of Instagram posts for survey promotion

- Promotional content for discussion group posted on Instagram

- Farah Lunat (Research Manager) & Nafeesa Bhatti (Lead RA) pictured during the Lancashire focus group

Time to Talk Day

We supported the LSCFT Research Team with an in person drop-in session to raise awareness of Time to Talk Day – an annual event marking the importance of having more conversations about mental health.

The drop-in session included engaging prompts to break down the stigma around mental health and promote conversations about taking care of our own wellbeing.

Attendees took park in a wellbeing quiz, mental health bingo and were able to write down their thoughts on a mood board.

- Official event poster used for promotion

- An abundance of cake & treats ready to be devoured by the staff at Lantern Centre

- Prompt invites which were used to invite colleagues/friends to the mental health drop-in

- Senior Research Facilitator Farah Lunat having a go at the mental health bingo

- Research Manager Karen writing down her tips on taking care of our mental wellbeing

- Research Information Officer Nafeesa writing down her tips on how to start conversations about mental health

- Examples of staff thoughts, feelings and tips around wellbeing, written down on the mental health mood board

Upcoming Events

We're proud to continue our support for International Women's Day, by using our social media platform to celebrate the achievements of women everywhere. The official theme for this year is #BreakTheBias, join us and be a part of this amazing movement

Keep up to date with all things ROSHNI-2 by following our official social media pages -

Twitter: ROSHNI2_
Instagram: roshni.2
Facebook: Roshni2info

We are delighted to support Perinatal Mental Health Partnership with the 6th annual Maternal Mental Health Awareness Week.
The weeklong campaign is dedicated to raising awareness of perinatal mental health difficulties faced by mothers during and after pregnancy.
The theme for the week will officially be revealed in March 2022.

We are delighted to also support Sangeet Foundation with their 'Hues of Happiness' event, in celebration of International Day of Happiness and the Holi festival.
The in-person event will include musical performances and Q&A sessions.
Senior Research Facilitator Farah Lunat will be joining the expert panel to talk about the importance of mental health.

NIHR | National Institute for Health and Care Research

Global Health Research Summary Impact Case Study

Guidance:
Impact and sustainability are key criteria for funding from the NIHR Global Health Research portfolio. Research impact is defined as the demonstrable contribution that research makes to society and the economy, of benefit to individuals, organisations and nations.

The aim of the summary impact case study template is to provide a consistent format for succinct, reliable, fact-checked summary impact case studies, **with only information included that is authorised to go in the public domain.** This template provides the opportunity to share how NIHR-funded research has improved practice, informed policy or delivered sustainable impact in partner countries. It should be possible to describe all information in a short 'elevator pitch', including:

1. Why the research is important
2. What the impact of the research has been, for example if it has influenced policy change, lead to the creation of a new product or strengthened research capacity
3. NIHR career progression (where applicable, usually only for NIHR Academy GHR case studies)
4. What the added value of the NIHR support has been (where applicable)
5. Quotes and media coverage where possible

Only include information in this summary case study template that is most relevant to the impacts being described. The bullet points are included as suggestions and not all bullet points will be covered in every case study.

The information added into the template below will be shared with our communication team to translate into simple and accessible 'summary case studies'. **Please include embedded links where you are referencing publications, articles, or other sources.**

If including quotes, our Impact/Monitoring Evaluation and Learning / Comms teams will work with award holders to collect quotes during the case study development or fact-checking process. Please ensure that there are clear permissions and sign-off has occurred to include these quotes in the public domain before inputting into this document.

Guidance from DHSC on case study format & content

- Everything should be as concise as possible, written in bullet point format.
- Where possible percentages should be expressed as 1 in 4 (24.6%) opposed to just the percent.
- Reference to meetings, publications, and dates should be specific. Please avoid phrases such as 'last week' or 'last year' and instead refer to Winter-23 / Mar-22
- Wherever there is a reference to 'additional', 'further' or 'more' please include the baseline.

Section 1: Why the research is important

What is the research about?

- A brief description in plain English terms of what the research was about and who did what
- How would you sum up this research to a stranger in 30 seconds?

This research was inspired by the *Thinking Healthy Programme* (THP), developed in Pakistan, as well as subsequent research integrating child development elements like Learning Through Play (LTP) as well as adaptations for group format delivery. These programmes address perinatal depression using culturally adapted cognitive behavioural therapy (CBT) delivered by non-specialist health workers. Building on this evidence, the earlier ROSHNI-D project (ROSHNI translates to 'light' in Urdu/Hindi) in the UK tested whether these culturally sensitive approaches could be meaningfully adapted for British South Asian women experiencing postnatal depression (PND). It demonstrated feasibility and acceptability, laying the foundation for the ROSHNI-2 project in the UK which evaluated this approach at a larger scale. The work was sponsored and hosted by Lancashire and South Cumbria NHS FT Trust in partnership with South Asian collaborators, community organisations and NHS Trusts, creating a model of bidirectional learning where interventions from low-resource settings were applied to improve equity in UK mental health care.

Rationale of the research

- Rationale for the research/support - why was the research important
- Condition/topic information supported by quantitative evidence (e.g. figures and statistics to validate this information) - prevalence (e.g. rare condition), baseline information of the problem under research, impact on people with the condition and/or in low- and middle-income countries (LMICs)
- Research population - was the research delivered where there was most need?
- Research design/delivery - type of design, geographical reach
- Co-funding, and collaborations/Community Engagement and Involvement (CEI)(if applicable- best examples)

Postnatal depression (PND) is a leading cause of maternal morbidity worldwide, with the prevalence and burden particularly high in low- and middle-income countries (LMICs) and among ethnic minority women in the UK. For instance, studies estimate that one in four and one in five postnatal mothers were living with PND in low-and middle-income countries, respectively. The economic burden is also immense; the cost of PND including maternal suicide in Pakistan alone was estimated at $16.6 billion in 2017 (Bauer et al., 2024). This high burden is also reflected among ethnic minority women in the UK.

Furthermore, women from British South Asian communities face additional barriers to diagnosis and treatment, such as with cultural stigma and mistrust, as well as limited access to culturally appropriate services. These disparities lead to poorer mental health and social isolation. Research in Pakistan through the *Thinking Healthy Programme* (THP) and Learning Through Play Plus (LTP-Plus) programme in Pakistan demonstrated that community health workers could deliver culturally adapted cognitive behavioural therapy (CBT) effectively, achieving recovery (i.e., reduction in depression scores at end of intervention) in three out of four women.

Building on this evidence, the ROSHNI-2 trial sought to test whether these approaches could

be adapted to the UK context, focusing on British South Asian women who are often underserved by conventional NHS mental health provision. The project was delivered across five centres in the UK (North West, Midlands, Yorkshire, London and Glasgow) in collaboration with community organisations, faith leaders and bilingual researchers. This design ensured both scientific rigour and strong community engagement, addressing an area of significant unmet need. If proven effective, this culturally adapted model has potential to be scaled across NHS services, particularly in regions with large South Asian populations.

Research Findings

- What were the key findings? Include evidence to validate where possible (e.g. embedded links, quantified evidence)

The ROSHNI-2 randomised controlled trial tested the effectiveness of a culturally adapted group cognitive behavioural therapy (CBT) programme, known as the Positive Health Programme (PHP), for British South Asian women with postnatal depression. Conducted across five sites in the UK (North West, Midlands, Yorkshire, London and Glasgow), the trial randomised 732 women (368 intervention and 364 control), primarily of Pakistani, Indian or Bangladeshi origin. In recognition of the high levels of stigma surrounding mental health within these communities, the intervention was intentionally framed as a “Positive Health Programme” to emphasise wellbeing and empowerment, and to position it as a training initiative rather than a therapeutic treatment. The results of this trial showed that participants in the PHP group were significantly more likely to recover from depression at four months compared with treatment as usual (49% versus 37%). By twelve months, however, recovery rates in the treatment-as-usual group had caught up, narrowing the difference between groups.

Engagement and retention rates were higher than expected, attributed to: bilingual research assistants, community partnerships and involvement of faith leaders. Qualitative findings highlighted that culturally adapted delivery (e.g., in Urdu, Punjabi, Bengali, Tamil and Gujarati), the use of peer-supported group sessions and family engagement helped reduce stigma and build trust in mental health services. Importantly, consistent with learning from the *Thinking Healthy Programme (THP)* and LTP work in Pakistan, engagement was strengthened when benefits for the child were emphasised alongside maternal wellbeing, which resonated strongly with participants and families.

Furthermore, success in disseminating the findings from this work has been observed through a variety of routes; for instance, a plain-English summary of the trial was published on NIHR Evidence, coverage in BBC Sounds as well as other media outlets. The parallels between ROSHNI-2 and THP/LTP demonstrate that culturally adapted, group-based interventions which integrate both maternal and child benefits can be effectively transferred between contexts, including from Pakistan to the UK, thereby improving access, cultural appropriateness and early outcomes in underserved populations.

- How did this research draw on learning from low- and middle-income country (LMIC) contexts, and why was this relevant to the UK setting?

The *Thinking Healthy Programme (THP)*, developed in Pakistan was designed to address perinatal depression using culturally adapted cognitive behavioural therapy (CBT) delivered by community health workers. By embedding psychological support into routine maternal care and employing a task-shifting model, THP demonstrated that such interventions could be both cost-effective and scalable in resource-limited settings. THP was adopted by the WHO in 2015, translated into seven major languages, and used in a variety of contexts in LMICs. These lessons directly informed the design of ROSHNI-2 trial in the UK, which applied the same principles to British South Asian women experiencing postnatal depression. South Asian women in the UK have been found to experience perinatal depression at rates nearly double that of the general population (roughly 25% to 10-15%), yet they remain significantly under-represented in NHS mental health services (less than half the expected uptake). This population represents one of the largest ethnic minority communities in the UK, but continues to face significant barriers in accessing conventional NHS mental health services due to stigma, language differences and lack of cultural tailoring.

By adopting bilingual delivery, incorporating cultural consultation and community engagement through faith leaders and family networks, the project demonstrated how LMIC-tested models could effectively be adapted to overcome barriers to access in the NHS. Crucially, these approaches are well suited to the UK health system as they are relatively low-cost, do not depend on large numbers of specialist staff, as well as can be integrated into existing perinatal pathways, all which align with NHS priorities at a time of unprecedented operational and financial pressures. This aligns directly with NIHR's strategic focus on tackling health inequalities, particularly improving access and outcomes for underserved populations.

The success of ROSHNI-2 highlights the potential for national application, both across regions with large Pakistani and South Asian populations, as well as more broadly for other underserved minority groups. This South-to-North knowledge transfer in global health shows that learning from research conducted within LMICs can lead to improvements in equity, scalability and responsiveness in high-income health systems. Furthermore, this work has informed the large-scale implementation and evaluation of the Learning Through Play Plus (LTP-Plus) programme in Pakistan, extending its application beyond depressed mothers to include fathers as well, through a partner-inclusive randomised controlled trial aimed at assessing its effectiveness and scalability in diverse family contexts.

Section 2: Outputs, outcomes and impacts - **quantify where possible**

- Outputs, research dissemination, and engagement with stakeholders to mobilise knowledge and support reach/uptake
- Individual awards and recognition, collaborations and partnerships
- Links with previous or further NIHR or external funding/support
- Influence on policy and practice beyond academia
- How, where and in what settings has the research been used and implemented beyond the study? Who has benefited - individuals, groups or wider communities? Local, regional, national or international?
- Improved health and welfare of people in LMICs - e.g., lives saved, improved treatment outcomes, reduction in disease prevalence
- Research Capacity Strengthening - individual, institutional and wider research ecosystem levels
- Community Engagement and Involvement

- Health and care system - e.g. improved efficiency, hospital bed days saved, improved service management, training implemented
- Innovation - e.g. IP, licensing products/software, spinouts, sales
- Economy, Efficiency, Effectiveness, Equity - e.g., cost savings realised, jobs created, showing value for money.

The ROSHNI-2 trial has produced multiple outputs across research, practice, policy, as well as community engagement and involvement (CEI). Findings from this work have been disseminated through publications in high impact journals, such as the Lancet, an NIHR Evidence Alert, as well as through media coverage in BBC Sounds, for instance. Over the course of the project and following its conclusion, impactful public and professional engagement was facilitated by webinars, podcasts and community-facing events. To illustrate these outputs and outcomes more clearly, the following section is organised under key thematic headings that highlight how the research has influenced across contexts and strengthened CEI:

ROSHNI-2 demonstrated that culturally adapted CBT, originally developed in Pakistan (Positive Health Programme (PHP)), could be successfully implemented in NHS services to address inequities in maternal mental health. This provided robust evidence that tailored perinatal interventions improves access and outcomes for underserved populations, strengthening the case for culturally adapted pathways within NHS maternity and perinatal mental health strategies. While adoption decisions vary regionally, the approach has informed discussions among NHS trusts in the North West about embedding more culturally tailored models.

As referenced above, ROSHNI-2 provides clear evidence of bidirectional learning. Core components from the *Thinking Healthy Programme (THP)* in Pakistan – including task-sharing, bilingual delivery, family engagement and collaboration with faith leaders – were directly transferred to the UK context. These approaches improved recruitment and retention, reduced stigma and enhanced recovery outcomes for British South Asian women. Conversely, the adaptation process in the UK generated lessons now being fed back into ongoing NIHR-funded projects in Pakistan, such as BURNS (NIHR203082), ACROSS (NIHR205540) and ABC (NIHR205561). These include strengthened fidelity monitoring, structured supervision frameworks and the integration of digital tools for group delivery. This two-way exchange illustrates how global health research can simultaneously strengthen equity in the NHS while reinforcing capacity and innovation in LMIC contexts.

ROSHNI-2 placed partnerships at its core working closely with local South Asian communities, third-sector organisations and faith leaders, who were central to delivery. This approach created sustainable networks of trust between NHS services and minority communities, relationships that can be leveraged for future interventions. Recruitment and retention rates were higher than anticipated, thereby reflecting the importance of co-production and CEI in improving trial delivery and subsequent service uptake.

The culturally adapted CBT based programme demonstrated early improvements in recovery rates (49% versus 37% at four months) and high levels of patient-reported satisfaction. Although the difference in depression recovery narrowed by twelve months, this reflected improvement in the treatment-as-usual group rather than a deterioration in the intervention arm. Additionally, parenting measures showed significant improvement at twelve months among those who received the intervention, suggesting wider relational benefits. These findings indicate that culturally adapted approaches may offer enduring benefits beyond symptom reduction, with potential to reduce service disengagement, enhance parenting capacity and improve efficiency by tailoring interventions to populations

most at risk.

The adapted intervention is low-cost compared to standard specialist-led therapy, with the economic evaluation confirming its cost-effectiveness within NHS thresholds. By addressing cultural and structural barriers faced by British South Asian women, the Positive Health Programme (PHP) directly contributes to NHS equity goals and offers a scalable, replicable model for other underserved populations. The societal costs of untreated perinatal depression are substantial, including impacts on maternal functioning, child development and long-term service use. ROSHNI-2 found that while direct healthcare costs were comparable across groups, improvements in parenting outcomes at twelve months point to potential downstream savings in child and family services. By enhancing recovery and relational capacity, culturally adapted interventions like PHP may reduce service disengagement, improve maternal-child trajectories, and alleviate broader economic burdens associated with untreated PND.

Overall, ROSHNI-2 illustrates how global health research can achieve measurable impact in both the UK and LMICs. The trial strengthened the evidence base for culturally adapted, group-based interventions, demonstrated cost-effective ways to improve outcomes for underserved groups and generated lessons now being integrated back into NIHR-funded projects in Pakistan. Together, these impacts advance NHS and NIHR priorities on equity, efficiency and international collaboration.

Bidirectional learning (South-North and North-South pathways)

- How did lessons from LMIC research (e.g., Pakistan) shape UK research, practice or policy?
- What specific mechanisms enabled this transfer (e.g., culturally adapted methods, CEI strategies, bilingual staff, community partnerships)?
- What impact did this have on NHS services, patient engagement or equity in the UK?
- Was there evidence of reverse flow back into LMICs or wider global health policy?

ROSHNI-2 provides one of the clearest examples of reverse innovation within NIHR's global health research portfolio. Lessons from the *Thinking Healthy Programme (THP)* in Pakistan fundamentally shaped the design and delivery of the ROSHNI-2 trial in the UK, demonstrating how interventions developed in LMICs can inform and strengthen NHS services and care models.

Several mechanisms arguably facilitated this learning and application within the UK. For instance, community engagement strategies pioneered in Pakistan – such as working with families, engaging faith leaders and tackling stigma before recruitment – were directly applied in the UK. Bilingual research assistants and culturally adapted materials (Urdu, Punjabi, Gujarati, Bengali and Tamil) ensured accessibility, while the use of peer-supported group therapy mirrored Pakistan's emphasis on community and relational support. In addition, fidelity monitoring and supervision models were adapted from UK practice and fed back into LMIC collaborations, creating genuine two-way exchange.

The impact in the UK was evident. Recruitment and retention of British South Asian women with PND were significantly higher than expected, thereby overcoming historic barriers to engagement with mental health services in the NHS. Participants reported that culturally tailored delivery reduced stigma and built trust, leading to short-term improvements in recovery rates (49% versus 37% at four months compared to treatment as usual). These findings have influenced local NHS trusts in the North West and were highlighted nationally

when the ROSHNI-2 trial was included as a good practice example in the IAPT BAME Positive Practice Guidance.

Furthermore, there is clear evidence of reverse innovation flowing back into LMICs. UK-led adaptations, such as the use of structured targets, strengthened supervision and integration of digital tools for group delivery – are now being applied in ongoing collaborations in Pakistan. These adaptations are enhancing implementation capacity and reinforcing the sustainability of interventions in LMIC contexts.

By embedding LMIC learning into the NHS while also reinforcing global collaborations, this project demonstrates how bidirectional research pathways can drive equity, innovation and system strengthening in both settings.

Section 3: NIHR Career Progression (where applicable, usually only for NIHR Academy GHR case studies)

- NIHR support - previous NIHR awards held or that you have been involved in, NIHR leadership training, etc.
- Were opportunities created for UK and LMIC researchers to develop leaderships through bidirectional collaboration?

The ROSHNI programme began with an NIHR Research for Patient Benefit (RFPB)-funded exploratory trial, which laid the foundation for the subsequent HTA-funded ROSHNI-2 trial evaluating clinical and cost effectiveness. This progression not only built a robust evidence base for culturally adapted interventions, but also significantly supported development opportunities for the Chief Investigator and co-applicants.

Professor Nusrat Husain, CI for ROSHNI-2, has since been awarded an NIHR Senior Investigator title and has played a key role in shaping international research strategy as a consistent NIHR leader. Professor Husain has been widely recognised for his contributions to mental health research and cultural psychiatry. He received the Royal College of Psychiatrists' Academic Researcher of the Year Award 2016 in recognition of his excellent work in improving access for marginalised communities to mental health care. In 2024, the University of Manchester honoured him with the "Making a Difference Award" for his significant work on the ROSHNI-2 trial.

Professor Nasim Chaudhry, co-applicant and supervisor on the ROSHNI trials, has applied key learnings to lead two NIHR RIGHT-funded projects in Pakistan (Burns Rehabilitation, Integrated Psychosocial Care for Comorbid Depression in Breast Cancer). Farah Lunat, Trial Manager, is currently progressing from leading trial delivery and CEI in ROSHNI to completing a PhD via publications, further embedding her expertise in global health research management.

The trial also fostered bidirectional capacity building between UK and Pakistan teams. Regular supervision and mentoring supported cross-site cohesion, while structured training strengthened trial governance, auditing and management capacity. The reciprocal model has had a lasting impact on both systems. This enabled the LMIC partner to successfully host larger NIHR grants, ensuring ROSHNI's legacy in global research development and leadership.

Section 4: NIHR's role and added value of NIHR support (where applicable)

- What did the NIHR specifically do here? (For example - We provided funding for this research through the Research and Innovation for Global Health Transformation (RIGHT) programme)
- Why was NIHR support so vital to the finding/discovery?
- Is there something that only the NIHR could offer, which made this project successful?
- Added value of NIHR support (e.g. innovative trial design, recruiting faster, delivering more effectively)
- How did NIHR support benefit the health and welfare of people in LMICs?
- Did NIHR support (or cross-award collaboration) specifically create the conditions for bidirectional learning between LMICs and the UK?

(around 100-200 words)

Section 5: Quotes and media coverage

- Where possible include supportive quotes about NIHR from research participants, health and care professionals, research charities, industry, and other stakeholders
- Where possible, include quotes that illustrate the significance of South-North learning for NHS practice or for underserved populations.
- Where case study focus is on an individual award (e.g. career development award) **quote must be included**
- Please insert links if there is any media coverage relevant to this NIHR funding support
- *Note to the user - please check with NIHR colleagues (see contact in table below) before using any quotes included below*

*The trial's impact extended beyond academia through **high-profile media coverage**, including:*

A BBC Sounds feature highlighting the lived experience of British South Asian mothers and the importance of culturally adapted care.

A Lancet Psychiatry podcast where Farah, Prof Husain and a PPIE representative unpacked the learning from the trial and wider implications.

ROSHNI-2 has catalysed national and international conversations on health inequalities in perinatal mental health. Its inclusion in the Royal College of Psychiatrists' Dean's Grand Rounds (February 2025) positioned the trial alongside Australia's E-PIMH telepsychiatry model, highlighting ROSHNI-2 as a leading UK example of culturally adapted care. The event brought together clinicians, researchers, and policymakers to explore scalable solutions for underserved communities, with Farah Lunat and Professor Nusrat Husain presenting on ROSHNI-2's design, outcomes, and implications for NHS commissioning. This platform amplified the trial's role in shaping equitable service models and informed future directions for global perinatal mental health systems.

These platforms amplified the voices of participants and researchers, fostering public dialogue, policy interest, and professional awareness across sectors. For instance, the quotes from research participants, found in Chapters 7 and 8 of the NIHR report, highlight the personal impact of the ROSHNI-2 intervention:

- *"Everything was really good. Can't be thankful enough, these sessions have really changed my life."*
- *"I am feeling so much better... I got a lot of confidence, and I was a bit hesitant to communicate with other people in public, but I don't hesitate now..."*
- *"...it was basically working on yourself, and trying to identify the problems you have to build your self-esteem back up, so that helped yeah. I did work on my self-esteem and also started saying 'No' when I wanted to."*
- *"I think if I would not be invited to that group, I would have gone for counselling, however, due to COVID and lockdown I would be stuck at home but being home, speaking online, and having that support and interaction was helpful for me. If I would not be invited to the group, I do not think I would be the same person I am today."*
- *"It was a treat honestly... good food, childcare I made friends learnt some very good things which help me in my daily life. Truly it was time for me, I will always remember it."*

Beyond research participants, these quotes below from Chapter 7 and 8 of the NIHR report show the value of the trial from a delivery and service perspective:

- **From a General Practitioner (GP):** *"Yes, I think so and it has (ROSHNI-2 trial) deflected so many GPs appointments and so many issues that we probably would have taken ourselves as we had very positive feedback from Roshni... So, in other ways it is impacting our workload and helping us to support these mums."*
- **On the "South-North" Learning Model (from a GP):** This quote perfectly illustrates the value of the peer-support model, which was inspired by the *Thinking Healthy Programme* developed in Pakistan: "I think it would (work) because it draws cultural relations of peer support South Asia and community anyways back home which they expect to have access to."
- **From a Positive Health Programme (PHP) Facilitator:** *"I think culturally adapted therapies for mental health are beneficial. The reason is that there are a few times when we speak to mums they open and say that the reason I am speaking to you is that you are speaking my language and this intervention is doing the same. It gives you a sense of understanding and not being judged."*

Lastly, the quotes below are provided largely by the LSCft Research Operations Manager, who spoke around their personal experience of this research area and the importance of the work they carried out:

- *"As a British-born Indian Muslim woman and the eldest of five children in a South Asian family, I am intimately familiar with the complexities of navigating identity, faith and culture."*
- *"As a teenager, I watched my own mother navigate pregnancy, postpartum and neonatal loss. Though she had lived and worked in the UK since she was 15, she*

lacked the confidence to advocate for herself... These experiences cemented my passion for women's health and later shaped my decision to dedicate my career to this field."

- *"Ethnic minority communities that are so often labelled as 'hard to reach' are, in fact, 'easy to ignore'."*
- *"ROSHNI is about so much more than clinical outcomes; it's a story of representation, inclusion and community empowerment."*
- *"Our study has proved that a culturally inclusive approach to research does work and has huge potential benefits for improving access to healthcare for underrepresented communities."*
- *"ROSHNI is an example of what's possible when we listen, adapt, and include and a reminder that heritage is not only something we celebrate, but something that here at LSCft, we are building upon to improve access to care."*

Further information

See the appendices below for more information on the code lists. *Please do not leave cells blank, if the cell is not applicable to the impact case study please put N/A.*

To determine HRCS codes - check award IDs in the funding and awards website OR NIHR Open Data to ensure alignment with the coding applied here.

Information required for back end of repository	
Award title	
Award ID	
Centre/s	
Programme/Scheme (no acronyms)	
CI/PI	
Professional background/occupation of CI/PI	
Funding amount (£)	
Funding start date (mm/yyyy)	
Funding end date (mm/yyyy)	
*NIHR Funding and Awards URL	
*Links to other awards with NIHR	
HRCS health category code(s)	
HRCS research activity code(s)	

Country(ies) of Activity (Downstream partner)	
Date summary case study last updated	
NIHRCC Impact/MEL contact	
*Link to full Impact case study	
Has the award holder reviewed, validated and approved the case study for use? (Yes/No)	
Are there any restrictions, sensitivities, or other things to consider regarding the use of this case study or the use of quotes? Please explain	

**To be filled in by NIHR Impact/MEL team*

Information required for the back end of repository - to be completed by 1B project lead	
Case study reference number	
Date added into repository	
Relevant NOF outcome	
Economist reviewed?	

Annex

HRCS health category codes

Blood
Cancer and neoplasms
Cardiovascular
Congenital disorders
Ear
Eye
Infection
Inflammatory and immune system
Injuries and accidents

Mental health
Metabolic and Endocrine
Musculoskeletal
Neurological
Oral and Gastrointestinal
Renal and Urogenital
Reproductive health and Childbirth
Respiratory
Skin
Stroke
Generic health relevance
Disputed Aetiology and Other

HRCS research activity codes

1. Underpinning research	5.3 Medical devices
1.1 Normal biological development and functioning	5.4 Surgery
1.2 Psychological and socioeconomic process	5.5 Radiotherapy and other non-invasive therapies
1.3 Chemical and physical sciences	5.6 Psychological and behavioural
1.4 Methodologies and measurements	5.7 Physical
1.5 Resources and infrastructure	5.8 Complementary
2. Aetiology	5.9 Resources and infrastructure (treatment development)
2.1 Biological and endogenous factors	**6. Evaluation of treatments and therapeutic interventions**
2.2 Factors relating to physical environment	6.1 Pharmaceuticals
2.3 Psychological, social and economic factors	6.2 Cellular and gene therapies
2.4 Surveillance and distribution	6.3 Medical devices
2.5 Research design and methodologies (aetiology)	6.4 Surgery
2.6 Resources and infrastructure (aetiology)	6.5 Radiotherapy and other non-invasive therapies

3. Prevention of disease and conditions	6.6 Psychological and behavioural
3.1 Primary prevention interventions to modify behaviours or promote well-being	6.7 Physical
3.2 Interventions to alter physical and biological environmental risks	6.8 Complementary
3.3 Nutrition and chemoprevention	6.9 Resources and infrastructure (treatment evaluation)
3.4 Vaccines	**7. Management of diseases**
3.5 Resources and infrastructure (prevention)	**7.1 Individual care needs**
4. Detection screening and diagnosis	7.2 End of life care
4.1 Discovery and preclinical testing of markers and technologies	7.3 Management and decision making
4.2 Evaluation of markers and technologies	7.4 Resources and Infrastructure (disease management)
4.3 Influences and Impact	**8. Health and social care services research**
4.4 Population screening	8.1 Organisation and delivery of services
4.5 Resources and infrastructure (detection)	8.2 Health and welfare economics
5. Development of treatments and therapeutic interventions	8.3 Policy, ethics and research governance
5.1 Pharmaceuticals	8.4 Research design and methodologies
5.2 Cellular and gene therapies	

Appendix C

ROSHNI-2 Positive Health Programme - Summary of Sessions

The Positive Health Programme (PHP) is a culturally adapted, low intensity CBT-based group intervention delivered over 12 sessions. The original version of the PHP was developed as part of **Dr Sobia Khan's PhD study** ***(Khan et al., 2019)***, in collaboration with British Pakistani mothers who shaped the early content, case studies, and cultural framing of the intervention. This initial programme was then tested in the **ROSHNI-D exploratory trial** ***(Husain, Lunat et al., 2023),*** which provided further insight into its acceptability and areas requiring refinement.

For **ROSHNI-2**, I worked closely with the wider research team to implement a second phase of cultural and practical adaptations to the PHP manual. This included revising case studies to reflect more diverse British South Asian experiences, updating graphics and formatting to improve accessibility, and refining session content in response to learning from ROSHNI-D and early feasibility work. These adaptations ensured that the PHP remained responsive to the linguistic, cultural, and social realities of British South Asian women living in the UK.

A version of this summary table has been published in ***Khan et al 2019*** - https://link.springer.com/article/10.1186/s12905-019-0712-7/tables/1 and in supplementary material in ***Husain et al, 2025*** https://www.journalslibrary.nihr.ac.uk/hta/KKDS6622#s3 .

1- Introduction to the Positive Health Programme	The PHP first session introduces the participants to the vicious cycle of depression using the ABC model. It explains how unhelpful thinking can affect behaviour and physical symptoms. It discusses examples familiar to British South Asian (BSA) women. The facilitators establish the ground rules (such as confidentiality) and explores the expectation from group. The concept of Cognitive Behaviour Therapy (CBT) and how to conceptualise feelings, thoughts and behaviours was explained and how to apply this to case scenarios used in the programme. It was important in this session to set the context in which the sessions will be based. Goal setting and its importance was explained to the group. South Asian women commonly present with more somatic symptoms and find it difficult to express their feelings and emotions and therefore in this session focus was given to the words women use to explain their distress, normalising low mood and understanding the terminology the women prefer. In addition, some words don't translate well into other languages which was why we spent time establishing preferred terminology and bringing awareness to what is depression and different ways it can present itself.
2- Pressures and expectations of being a woman	This session delves into the cultural expectations placed upon BSA women, where they often find themselves navigating the roles of caretakers for children and homemakers, which are considered their primary responsibilities. Additionally, a significant number of these women live in joint family homes, where they carry the

	additional duty of caring for their elderly parents-in-law. Such expectations often expose them to undue stresses and pressures. The session focuses on multiple roles a woman takes in a South Asian home and the conflicting roles of power in the home. There is discussion on decision making involving the family as a whole and the pressures of children's upbringing in a joint family home. Case studies were used in this session and others to allow women to be able to relate and apply concepts to their own situations. Activities focus on building confidence and encouraging positive thinking when faced with pressure. Within these activities, the facilitators encouraged discussion on the changing role of women and the cultural differences when discussing pressures and expectations. Often the women would help one another break the barriers and reduce the pressures, many of them were in the mind set of 'if you reduce it this week, so will I – let's see who can be kinder to themselves and focus on wellbeing instead'.
3- Understanding and managing self-esteem (Part 1)	This session focuses on raising awareness about the concept of self-esteem and how past experiences along with the cultural and societal pressures and expectations (discussed in the previous session) can impact self-esteem. Using the case scenario, participants were encouraged to discuss how unhelpful thought patterns and behaviour could contribute to maintain low self-esteem. Following this, women in the group were encouraged to reflect on their own self-esteem and identify factors associated with their low self-esteem. Helping the women to recognise when/if there was ever a turning point where they recognised their self-esteem reduce – identifying triggers and challenging negative thoughts, e.g., where is this stemming from? Highlighting positive support around them and embracing positive language around the home, especially in regards to their self-image and self-worth. Discussions naturally led to talks about generational trauma, it was highlighted how these roles discussed in the previous session were usually moulded by what women are taught from their own mothers who were often immigrants and had a traditional mentality. The session also discusses how negative self-esteem is maintained and what cultural factors, responses to situations, day-to-day events and their interpretation leads to low self-esteem being maintained.
4- Understanding and managing self-esteem (Part 2)	Continuing with the previous topic, this session aimed to teach participants skills to help improve their self-esteem. This focused on the ABC of our thoughts and behaviours in relation to our self-esteem. The group activities provided the participants with the opportunity to explore culturally appropriate and relatable examples for achieving good self-esteem. Examples were given in the manual to generate discussions.
5- Assertiveness and confidence building	This session was aimed to help the participants built their assertiveness and confidence. It built on the self-esteem work, covered in the previous sessions, with explanation of how low self-esteem can lead to low self-confidence. The concept of assertiveness was discussed in detail and the distinction between assertiveness and aggressive

	was highlighted. Generally, within South Asian communities, women live in joint family homes where patriarchal and hierarchical family structures limit their autonomy and expressing one's views and opinion could be perceived as being confrontational or exhibiting lack of obedience. The session would pay special attention to how in the South Asian culture it can be seen as disrespectful to say "No", we discussed how sometimes we can't say "No", but we can decline a request in a respectful manner to protect emotional wellbeing. Using the case scenarios, assertiveness within the power struggles was explored in more detail, and ways to learn skills to be assertive in a positive way was explored and practised. Role-play and activities of 'saying no' included the sandwich technique of positive assertion, being confident and polite but setting boundaries. Sandwich approach – 1. Acknowledge and validate the request, e.g., 'Thanks for thinking of me when needing help with the cooking, I'm sorry to hear you're struggling this week'. 2. Respond to question/conversation i.e., yes, or no, with a reason if appropriate – 'Unfortunately, I have many things on this week and I wouldn't have a free window to help with your cooking'. 3. Offer an alternative/solution (helped the women to problem-solve themselves and promote this also), i.e., 'Have you tried asking your mother-in-law or sister if they could possibly help you this week? I hope you manage to find someone'.
6- 'Keeping up with the Jones's'	This concept was explored in the session and described as 'Keeping up with the Chaudhry's' to appeal to a BSA audience. In many southern communities, prosperity is often assessed based on factors such as the neighbourhood you reside in, the size of your home, the achievements of your children, and the possession of material wealth. Unfortunately, this can lead to feelings of inadequacy and failure among those who may not be financially affluent. This session highlights themes such as 'competing with others, feeling insecure and jealousy' through case scenarios. The session related this concept back to popular dramas as the South Asian drama and film industry is a great way for topics to feel more relatable as they address common family dynamics. The session looked at unhealthy thinking patterns when comparing ourselves to others, the feelings of jealousy and envy that may arise and how to overcome self-defeating thoughts. Using group feedback to encourage healthy thinking and behaviour.
7- Religion and Spirituality	Religion and spirituality are important components of the BSA culture. Conversations in this session discussed how different religions viewed mental health, the positives of spirituality and also the challenges of guilt in the context of religion. The group rules were emphasised again for this session and a focus on learning and showing respect for each other's beliefs. The facilitators explained how each of the main religions within the group (Islam,

	Hinduism, Sikhism) view depression and the teachings associated with this. The session aimed to identify any negative beliefs such as 'being punished for sins' and how to use spirituality to increase inner calm. The groups were conducted as multi-faith groups and women were able to share their beliefs and celebrate their differences as a group.
8- Breaking Social Isolation & Building Social Networks	Many first-generation South Asian immigrant women find it challenging to access mainstream social networking facilities because of cultural and linguistic barriers. As a consequence, they may experience a lack of social support, which can be detrimental to their wellbeing and integration into the broader community. The session explored the importance of social support as a protective factor for emotional health. It provided insight into daily opportunities – that work alongside the day-to-day routine of BSA women. Discussion around how new friendships can reduce social isolation and overall wellbeing. We would always emphasise that the women attending took out the time weekly to attend the sessions so would it be possible to keep this time aside to do something for themselves after sessions have ended.
9- Exercise, Looking Good and Building Motivation	The weight of perceived expectations from family, society, and the influence of social media has placed women under tremendous pressure to be perfect new mothers while also maintaining an impeccable appearance. Unfortunately, this burden of expectations causes distress for the majority of women, particularly in South Asian communities, where making unempathetic remarks about one's appearance is often deemed acceptable. This session focuses on this crucial issue and the need to foster a more compassionate and understanding environment that supports and uplifts women during this significant phase of their lives. Participants were encouraged to explore the relationship between health, exercise, and improved mental wellbeing and awareness was raised about ways of exercising that are acceptable and manageable to new mums. We were fortunate to have great support from the local community, and professional personal trainers, yoga instructors, and dance instructors joined the sessions to give women a practical class with tips and demonstrations.
10- Relaxation: "Taking time out"	The notion of prioritising oneself and taking time out is frequently burdened with feelings of guilt among South Asian women. This session aims to emphasise the significance of self-care for the overall wellbeing of individuals and, in turn, its positive impact on the children who depend on them for care and support. The session helps participants recognise the value of self-care, and how they can better fulfill their roles as caregivers and lead healthier, more balanced lives for themselves and their families. Through discussion within the group, it explores barriers to relaxation by exploring the daily routine of the BSA women and practical activities that can help reduce

	stress by engaging the interests of women. This session also included practical activities such as yoga, mindfulness and breathing exercises and this was guided by participants and what they wanted to try/discuss.
11- Discussion	A session dedicated to revisiting previous topics in the course that may be helpful to the group. In this session, women were able to raise any topics not discussed in the sessions or opt to revisit any of the previous sessions. We would encourage self-reflection, revisit goals, motivation to implement techniques, how comfortable they felt etc.
12- Award ceremony & party	The final session celebrates the group's achievement in completing the Positive Health Programme. Certificates are given to all women and the session is a chance to reflect on their progress. Women dressed up for the session, invited family members if they wanted to, shared their reflections on the 12 weeks together and spoke of their goals. The sessions received great media coverage as a celebration of the commitment of these women in attending the sessions, working on their emotional health but also their contribution to research and the wider goal of enhancing maternal mental health services for their community.

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BMC Women's Health

RESEARCH ARTICLE Open Access

Culturally-adapted cognitive behavioural therapy based intervention for maternal depression: a mixed-methods feasibility study

Sobia Khan[1], Karina Lovell[2], Farah Lunat[3], Yumna Masood[4], Sadia Shah[3], Barbara Tomenson[5] and Nusrat Husain[6*]

Abstract

Background: British Pakistanis are one of the largest ethnic minority groups living in the UK, with high rates of maternal depression being reported in this population. Evidence suggests that culturally-adapted Cognitive Behavioural Therapy (CBT)-based interventions for depression, may improve clinical outcomes and patient satisfaction. This study was conducted to develop and test the feasibility and acceptability of a culturally-adapted, CBT-based, manual-assisted intervention in British Pakistani mothers experiencing maternal depression.

Methods: A mixed-method feasibility study that included qualitative interviews followed by the development of a CBT-based intervention for mothers with mild to moderate depression. Following the qualitative interviews, a CBT-based intervention called the Positive Health Program (PHP) was developed and delivered consisting of 12-weekly sessions. A before and after design was used to explore the feasibility and acceptability of the Positive Health Programme.

Results: A culturally-adapted CBT-based group intervention (PHP) was acceptable to this group and improvements were reported in depression and health-related quality of life. The women's understanding of 'depression' as a general consensus was in physical terms, but with an onset triggered by psychosocial causes. The most commonly reported factors contributing to depression were marital disharmony, lack of social support, and financial difficulties. Past help offered was primarily antidepressants, which were not welcomed by most of the women. A lack of availability of culturally sensitive interventions and the limited cultural sensitivity of NHS staff was also reported.

Conclusion: This study provides preliminary evidence for the feasibility and acceptability of a CBT-based culturally-adapted group psychological intervention for British Pakistani mothers.

Trial registration: Study ethics registration number: 10/H1005/62 (University of Manchester).

Keywords: Maternal depression, Cognitive Behavioural therapy, Cultural adaptation, British Pakistani women, Group psychological intervention

Background

Maternal depression affects women in all nations and across cultures [1–4]. In the 'Saving brains' project, Grand Challenges Canada have emphasised on better maternal health, better protection and responsive caregiving for improving early child development, particularly in the first 1000 days of life of the child [5]. Research has identified a lack of social support and marked difficulties particularly in marital and close relationships as key factors for maternal depression [6, 7]. This is reported to be particularly evident in Pakistani [8] and British Pakistani women [6, 7]. The consequences of maternal depression are significant; it may inhibit a mother's ability to respond sensitively to infant cues [9, 10] which is vital for infant growth and development [11], and may result in poor cognitive [12, 13] psychosocial and physiological outcomes [14, 15]. In addition, research in middle and low income countries has suggested an

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association between maternal depression and child growth impairment [16–18].

Explanatory models of illness encompass a person's ideas about the nature of their problem, its cause, severity, and prognosis and treatment preferences [19]. Disagreement between patients' and professionals' explanatory models may affect help-seeking behaviour and treatment adherence. A study conducted by Karasz reported that South Asian immigrant women viewed depression quite differently from White women [20]. White women attributed depressive symptoms to a biological cause such as "hormonal imbalance" or a "neurological problem" whereas South Asian women interpreted the symptoms as a reaction to "life problems" or "situational stress" [19].

An experimental vignette study conducted by Burt and colleagues identified that British Pakistanis have higher General Physician (GP) consultation rates compared to other ethnic groups [21]. Despite this evidence, a majority of South Asian mothers with common mental disorders are not identified by their GPs [22]. This may be due to difficulties in communication, cultural differences in presentation of symptoms [22], or different explanatory models between the physician and the patient, which often results in the patient remaining undiagnosed and untreated [23, 24]. Another possibility is cultural stereotypes that can mislead diagnosis and different treatment pathways [25].

Gater and colleagues reported the efficacy and acceptability of a culturally-adapted social group intervention [26] in British Pakistani women. It was reported that the social functioning and satisfaction levels of the women improved significantly with social treatment as compared to medical treatment only [26]. Evidence suggests that psychological interventions such as Interpersonal Psychotherapy (IPT) and CBT are effective in the treatment of maternal depression. [27, 28]. In order to improve the diagnosis and treatment of maternal depression, it is important to understand the experience of depression in British South Asian women. This study presents British Pakistani women's experiences of depression, their explanatory models about depression, and their views about the type of help they may find acceptable, through in-depth interviews. The study also explores the acceptability and feasibility of a CBT-based, manual-assisted intervention called the Positive Health Program (PHP) in this group of women.

Methods

Study design

This was a mixed-methods feasibility study. Initially qualitative interviews were conducted to explore the women's experiences of depression, their explanatory models about depression, and most appropriate help they may find acceptable. These women were invited to take part in the feasibility study, with assessments before and after the group intervention to compare the differences in severity of depressive symptoms and quality of life scores. Mothers were approached and screened using the Edinburgh Postnatal Depression Scale (EPDS) [29] after informed consent was obtained.

Inclusion criteria

British Pakistani mothers aged 18 years and above, scoring ≥12 on EPDS.

Exclusion criteria

Women diagnosed with physical or learning disability, postnatal or other psychosis or actively suicidal.

Sample

Those British Pakistani mothers, who had taken part in our earlier cohort study on social stress and depression in the ante-natal and post-natal period [6], were approached for participation in this study. Out of the total 47 depressed mothers identified residing in Central Manchester, only 36 could be contacted, so they were approached by the research assistant and given information about the current study. The recruitment of participants took place from October 2008 to February 2009. Participants were assessed by a trained bilingual researcher fluent in English and Urdu. The assessments took place at the participants' homes. Following informed consent, the 36 women were screened for depression using the Edinburgh Postnatal Depression Scale (EPDS) [29]. Out of the 36 participants, 18 women scored ≥12 on the EPDS, with the diagnosis of depression being confirmed using the Clinical Interview Schedule – Revised (CISR) [30]. Out of the eighteen participants, three opted out due to work commitments and time constraints and a total of 15 women agreed to take part in the study.

Data collection and analysis of the qualitative interviews

Initial data was collected through in-depth interviews. The interviews topic guide was developed through discussion within the research team and the existing literature. Key areas explored were, perceived causes of maternal depression, what help women had previously received for maternal depression and the type of help they would like to receive. All interviews were digitally recorded and transcribed verbatim. Data were analysed using framework analysis, consisting of familiarisation of the data, identification of a theoretical framework, indexing, charting, mapping and interpretation. Following detailed readings of the transcripts, themes and sub-themes were identified and a thematic framework was developed. The coding framework was then applied manually to the interview transcripts and then pasted to the excel spread sheets. Using the spread sheets, the study team (SK & KL) compared and contrasted various subthemes to finalise the theoretical table.

Development of the intervention

The development of the group psychological intervention, involved a process by which findings from multiple data sources and methods were combined to obtain in-depth understanding of the specific issues in designing and delivering the proposed culturally-adapted intervention for British Pakistani mothers. Data was reviewed and synthesised, with this process relying heavily on the information obtained in the earlier conducted qualitative interviews which explored the views about a feasible and culturally acceptable psychological intervention for depressed British mothers of Pakistani origin. The group sessions were conducted at a Children's Sure Start Centre in Central Manchester to provide an easily accessible location with appropriate childcare facilities for mothers.

The intervention (Positive Health Programme)

The culturally-adapted group intervention is based on the principles of Cognitive Behavioural Therapy (CBT). The study participants decided to call it the Positive Health Programme (PHP) (Table 1). The programme involved 12 weekly sessions facilitated by a research therapist who led the group with some training in CBT and leading depression groups using CBT skills and principles. Regular supervision was provided by a senior CBT therapist (KL) and a senior psychiatrist (NH). The sessions lasted approximately 60–90 min and involved group discussions, case scenarios, individual goal setting, and skill-based activities. The programme was designed to be simple and pragmatic which could be delivered by an individual trained in mental health and the principles of CBT [31]. The focus was on keeping the programme culturally appropriate. The key elements covered in the

Table 1 Elements of the Positive Health Programme (PHP)

Positive Health Programme (PHP)		
Theoretical basis	Based on principles of cognitive behavioural therapy (CBT)	Based on the previously mentioned findings and the literature review of empirical culturally based therapies for depression, cognitive behavioural therapy (CBT) was taken as the most suited approach that could be adapted for use with British Pakistani women. The 'here and now' problem solving CBT approach was felt to meet the requirements reported above and in the qualitative interviews.
Delivery	Minimally trained clinical staff, health research facilitators, mental health graduates such as assistant psychologists, IAPT psychological wellbeing practitioners. Intervention is simple enough to be delivered by anyone trained in mental health.	Rahman (2007) devised the following requirements for delivery: 1. Participant = family level • Should focus on overall maternal health rather than maternal depression • Should focus on the identified maintaining factors for depression • Should be active and empowering • Should be skill based 2. Delivery and facilitation level • Should be culturally sensitive • Should be simple and pragmatic • Should avoid stigmatisation 3. Health system level • Should be evidence-based • Should move away from 'medical model' to a 'Psychosociospiritual' model • Should be community based • Should be culturally adapted • Should be cost effective
Structure of the intervention	12 sessions, each session approximately 60–90 min	Group CBT based manual with step-by-step instructions for conducting each session. Activity workbooks and hand-outs for mothers
Structure of the group	Group welcoming and connecting, introduction to the session topic, group discussion, engaging in skill based activities, planning individual goals, and homework setting session	On-going training and supervision by clinical staff including a senior CBT therapist and a senior psychiatrist
Areas covered in the sessions/ manual	• Identifying the pressures and expectations of being a British Pakistani woman • Understanding and managing self-esteem • "Keeping up with the Joneses" "Chaudhry's" • Exercise, looking good and ways of building motivation • Religion and spirituality • Relaxation: "Taking time out" • Culturally sensitive assertiveness and confidence building • Breaking Social isolation and building social networks • Practising CBT and assessing change	The ABC model of CBT was used to demonstrate the relationship between thoughts, feelings and behaviour in each session. Specific interventions included psycho-education, behavioural activation, problem solving, relaxation, and managing negative thoughts.

manual are detailed in Table 1 (the manual is available on request).

Assessments

Participants were assessed at baseline, 3 months (end of intervention), and 6 months after baseline. Uptake, adherence, and acceptability were chosen as the feasibility parameters for this study. These were measured by the participants' attendance records for the group sessions. Participants who were absent were followed-up to explore reasons for their absence.

Edinburgh postnatal depression scale (EPDS) [18]

The presence of depression was assessed with EPDS at baseline, week 4 and week 8 of the intervention, end of intervention (3 months) and 6 months after the baseline assessments. EPDS is a 10-item, self-report scale and has been used among women in Pakistan [32] and British Pakistani women [31]. The EPDS has been validated in this population and results suggest that the EPDS has good psychometric properties [33].It has also been used and validated with mothers 0 to 3 years of children [34, 35].

The clinical interview schedule revised (CIS-R) [30]

This structured interview was used to confirm the diagnosis of depression. It has 14 sub-sections and has been previously used with British Pakistani women [26].

EuroQol (EQ-5D) [36]

The EQ-5D provides a descriptive profile of health-related quality of life and a subjective overall rating of the participant's own health status on the day of administration by means of a visual analogue scale. In an earlier UK based study, the EQ-5D was used with British South Asians in a primary care setting [37].

The dyadic adjustment scale (DAS) [38]

This 32 item self-report measure was used to assess marital relationship. Four factors are reported: dyadic satisfaction, dyadic consensus, dyadic cohesion, and affection expression. This scale has not been used previously with British Pakistani depressed mothers.

Multidimensional scale of perceived social support (MSPSS) [39]

This is a 12-item instrument designed to assess perceptions about support from family, friends and a significant other. The scores for each item can range from 1 to 7. A high score indicates high levels of perceived support. In a study of maternal depression in Pakistani women, MSPSS was found to have good construct validity, and the internal consistency (Cronbach's alpha) of MSPSS was 0.92 [40].

Satisfaction

This 6-item adapted scale called "Satisfaction with support and treatment" is extracted from the full-scale Verona Service Satisfaction Scale [41], which was used in the previous depression trial with British women of Pakistani origin [26]. At the end of the intervention, participants were asked for their self-rated satisfaction with treatment based on a three-point ordinal adapted scale derived from the Verona Service Satisfaction Scale [41].

Statistical methods

Since the sample size was too small to confirm the data distribution, non-parametric tests were used for all measures. Median scores at all time-points for each score are presented, and changes from baseline to all follow-ups have been assessed using the Wilcoxon matched pairs signed-ranks test.

Ethical approval

Ethical approval was granted by the Local Research Ethics Committee and the University of Manchester (registration number 10/H1005/62).

Cultural adaptations

Previous research by our group and our colleagues has shown that adaptations need to be implemented within CBT for it to be effective for South Asian women. A study by Naeem et al. [42] reported that these adaptations need to focus on three main areas, i) awareness of the cultural issues and getting ready for relevant therapy ii) assessments and engagement of the population with the therapy iii) adjustment in therapy. Therefore, adaptations in this study were done in-line with the above mentioned study [42], with some guidance from other studies by our colleagues, such as the study on cultural adaptation of CBT for psychosis for British South Asians [43], guidance from culturally sensitive CBT for depression in Pakistan [44] and also our other work in Pakistan [33, 35]. With the help of qualitative interviews and understanding explanatory models about depression and suggestions given by mothers about the type of acceptable help the central adaptations made to the manualised intervention were; South Asian CBT jargon, culturally appropriate assignments and homework, folk stories and examples with considerations to religious beliefs and understanding the ABC model using culturally appropriate stories.

Results

Qualitative results

Fifteen of the 18 mothers who fulfilled the inclusion criteria agreed to take part in the in-depth interviews. They were interviewed at their homes; each interview lasted approximately 40–80 min. Their age ranged from 23 to

41 years with a mean age of 33 years. The women had an average of three children, ranging from 2 to 5 years. Eight women were first generation migrants and seven were born in the UK. Twelve women were living with their husbands, two were divorced and one separated. At the time of the interview, 11 women were homemakers, two worked full-time and two worked part time.

The analysis of the data revealed three themes described below:

- The perceived causes of maternal depression
- Previous help sought for maternal depression
- The type of help needed for maternal depression

The perceived causes of maternal depression

All women described the term 'depression' through a description of somatic symptoms and a psychosocial model with spiritual explanations. The main social causes reported for their depression were lack of support and marital problems, social isolation, financial hardship, bereavement, low self-esteem, and difficult family relationships particularly with their husband.

> *"It's the panic attacks, the shivers. Sometimes I'd be watching the TV and I would feel my heart thumping, and I would think hang on I'm not thinking about anything, then what's the reason? I can unnecessarily get the panic attacks, constant migraines, three times a week. That is not normal. I don't know what triggers it because sometimes I'm not thinking anything at all" (P1).*

Lack of support

Lack of social support was the most commonly reported factor for depression. A change in these women's family structure, from living in an extended to a nuclear system, may have contributed to depression as all of the participating women in this study lived in a nuclear household, and potential support networks may have been lost.

> *"I'm not getting any support or the support that I need. People do come to me, help me out but I haven't got the support that I need. My mum just recently passed away in June. I've been really depressed since then. I've had no support". (P10*)

Difficult relationship with the family

Some of the women spoke openly about the negative influences of their mothers on their mental health. Difficult relationships with not only mother in laws but also their own mothers and the mother's lack of understanding and denial of participant's depression often led to many of these women suffering in silence.

> *"I can only talk about my mum. If she sees me crying, she says, "Why are you crying? There's nothing wrong with you. You're just being yourself, you do this all the time, you cry for no reason, you're happy, you're here, you have a nice husband, and you have no major responsibilities like I did so pull yourself together". (P14)*

Marital difficulties

Marital difficulties have been highlighted as a prominent issue in this group. Poor marital relations not only equated to a lack of practical and emotional support from the husband but often involved domestic violence. The women expressed the need to stay in a poor marriage for the sake of their children's future and a lack of options to change their circumstances because of financial dependence on their husband.

> *"When I see my life, I feel like throwing him out of the house before dark. But when I see him with the kids, I can't do that. He is there for them. Tomorrow if I separate and I can't provide for my kids and they go astray, what will I do? If they start staying out till late, how will I discipline them, what would I do if they don't listen to me?" (P13)*

> *"I think it's mainly these marriages. Because in our marriages everything stays within the four walls other people don't know what's going on. Even though at times when we have been screaming, the voices don't go outside". (P13)*

Low self-esteem

The role of low self-esteem in the development of depression was an important factor. The factors associated with low self-esteem varied from dissatisfaction with appearance to a lack of career achievements. Low self-esteem due to poor marital relationship was also evident.

> *"He makes me feel bad about myself? Why am I so ugly that he doesn't want to know me, but it's been so many years now since we've been married. I was a confident person at that time, but over the years I lost it. Then I did a self-esteem course and that picked up my confidence but then I lost it again". (P10)*

Religion and spirituality

Some spiritual elements were perceived to contribute to depression. Some women in this study stopped their religious practices as a result of feeling guilty and thoughts of being punished by God for their past sins. God was no longer seen as the source of support and women ended up with continuing feelings of remorse and persecution. These feelings were reported by the women as a perpetuating factor in the persistence of depression. The underlying mechanisms for the fear of punishment from God often arose from feelings of guilt for various reasons, for example, undergoing an abortion, rebelling against parent's wishes, and neglecting elderly parents. The fear of punishment and thoughts of eternal suffering contributed to symptoms such as hopelessness and helplessness.

> *"Sometimes, I think I am being punished by God for what I did to my dad, making him upset you know, getting married without his will. That's why, even though I've got kids now, healthy kids, I'm still not happy". (P11)*

Financial problems

Women described feeling low in mood and stressed due to financial difficulties. Their lack of financial contribution to the household caused these women to feel unworthy and disempowered, and this sometimes contributed to marital disharmony.

> *"Our financial worries make me sad. We are so dependent on my husband's brother. He supports us so much. I sometimes wish that we didn't have to ask anyone or live on someone else's money. It's shameful in our community isn't it? So I do feel very sad and ashamed in front of my other relatives. I didn't ever imagine a life like this". (P2)*

Previous help sought for depression

The majority of the women were reluctant to take antidepressant medication due to side effects. They perceived anti-depressants as "numbing the pain" rather than addressing the issue. Antidepressant medication was prescribed initially to 11 of the 15 participants. However, seven out of the 11 participants were also offered counselling at some point. Four out of the 15 participants had never approached the GP for any type of help for their depression as it was seen futile and the type of help that was available was not perceived as useful.

Out of the seven participants who were offered counselling, only three attended the counselling sessions. The counselling was seen as helpful to a certain extent; however, it lacked cultural knowledge and sensitivity which in turn made all three of the participants not attend further sessions. These women emphasised the importance of having a culturally sensitive therapist belonging to the same culture as they were.

> *"I got treatment at that time, when I had my first child. I was really bad at that time. I was depressed all the time, just really bad. It got worse with my second child. They gave me some antidepressants. I didn't really take a lot of them. I didn't want to. I just didn't want to take any tablets." (P11)*

The types of help British Pakistani women want for maternal depression

The majority of the women favoured a group psychosocial treatment to reduce social isolation and to increase social support. Although women wanted the treatment to have a supportive element, support alone was not seen as sufficient to overcome depression. The women expressed the need for a more directive and problem focussed approach and wanted help to improve self-esteem and self-confidence, to learn coping skills such as assertiveness to improve marital relationships, problem solving, time management, relaxation, and anger management. The participants also wanted help with managing negative thoughts.

> *"I would love that (group treatment), just to share your emotions with people, talk to people because I can't just go out there and talk to anybody. I can't find anyone who can mix with me" (P11).*

Most women showed an interest in exercise, building social networks, practising religious activities and emphasised that religious activities should be incorporated in modern day psychosocial interventions. The women believed that prior to the onset of depression their faith in religion had helped them to cope better with life difficulties.

The lack of appropriate support with marital difficulties was raised by women who were experiencing marital problems. These women highlighted the need for some specific services for Pakistani men as they were seen as the main cause of their depression. According to these women, not enough is being done to engage Pakistani men into treatments which may help with marital problems.

The perceived barriers to attending treatment were lack of transportation, unavailability of childcare, language, workload, time of day, and often the husband. Because of lack of autonomy to movement and decision making over half of the women believed that their husband would prevent them from receiving any treatment for depression. There is lot of stigma about mental health and concerns about the community grapevine. This largely relates to the concept of 'Izzat' meaning family honour that is very important in Pakistani families. Keeping face and maintaining the family honour results in a lot of things being kept hidden and a need to maintain appearances within the community and thus issues such as mental health problems can be covered up.

It was suggested that the treatment for depression should be advertised to wider family members as an educational course for positive ways of coping with motherhood and stressing the beneficial outcomes for children. This was important because if the focus is on the child rather than the mother it would be more acceptable to the extended family and the wider community and; thus, there will be little stigma attached which could affect the "honour" of the family. It was also suggested that promoting interventions in such a way may also help to reduce the stigma associated with mental health issues and treatment for mental health problems [29]. Therefore, a non-stigmatising name for the therapy was considered important.

> *"I mean if my husband finds out that this is a group for (depressed) women, he's not going to let me come to it." (P11).*

Quantitative results

Demographics

Fifteen women consented to participate in the intervention, out of those 10 attended 4 or more group intervention sessions. They were aged between 25 and 40 years (mean age, 33 years), 8 were married, one was divorced and one was separated. The mean number of children was 3, ranging from 2 to 5, all except one was a homemaker, 5 were first-generation migrants and five were second-generation migrants. All participants were educated up to at least GCSE.

Attendance at the positive health Programme (PHP)

Attendance levels were used to assess the acceptability of the intervention. The PHP group intervention was designed to have 12 sessions, but one session was cancelled due to unavailability of a room at the children's centre. The content of this session was incorporated in the remaining sessions. A total of 10 of the 15 participants attended 4 or more sessions. Two attended less than 4 sessions and 3 did not attend any of the sessions. The group attendance was noted by one of the group facilitators, the absentees were followed and a note of reasons for their absence was made. Of the three women who did not attend any session, one was physically ill, second was back in full-time work and third could not make travel arrangements.

After developing consensus with our colleagues working on culturally adapted CBT and brief psychological interventions [44–46] it was decided that those women completing four or more sessions would be termed as 'completers'.

Depressive symptoms

Reduction in depressive symptoms was measured using the EPDS at 5 different time-points: baseline, intervention week 4 and 8, end of intervention and 6 months after baseline assessment. The median EPDS score at baseline was 20 which reduced to 11.5 by week 4 and to 11 by week 8. The drop in EPDS scores was sustained at 6 months after baseline with a median score of 5.

Service satisfaction

Of the total participants ($n = 15$), 10 attended 4 or more sessions and were called 'completers'. The majority of completers were satisfied with the intervention; four highly satisfied, five fairly satisfied and one not satisfied. Six of them said they would 'definitely recommend' this therapy to others and four said they 'might recommend'.

Marital relationships

The DAS scores showed significant improvement ($p = 0.01$) in marital relationships with the intervention. The mean DAS score at baseline was 55 (SD = 30.3), which increased to 78 (SD = 34.8) at the end of intervention, and was sustained at 76 (SD = 32.1) at 3 months post-intervention follow-up.

Social support

There was an increase (indicating improvement) in total MSPSS scores in each of the three subscales from baseline to end of treatment, which was maintained at 6-month follow-up (Table 2). This increase in the scores reflected increase in perceived support from family, friends, and significant others.

Quality of life scores

EQ-5D score showed a significant improvement, in health status of mothers, with the intervention. EQ-5D scores improved from baseline (median = 55) to end of treatment (median = 72.5, $p = 0.036$), and was maintained at 6-month follow-up (median = 70, $p = 0.037$).

Discussion

Feedback from the brief, adapted Verona Service Satisfaction questionnaire showed that the Positive Health Program (PHP) is an acceptable and feasible intervention for British Pakistani mothers. Two-third of the women (10/15) completed the intervention and attended four or more sessions. Maternal depression has been reported as hard to treat because of its longstanding and complex nature [47]. Considering this is a hard to engage population, the attrition rate for this group intervention was relatively low (66% were completers), similar to that reported in a previous study with persistently depressed British Pakistani mothers in which 50% of the mothers were completers [48]. Several factors such as using familiar language, culturally aware therapists and facilitators, childcare facilities, and transport assistance helped to engage and retain participants in the study. All these factors were initially identified through qualitative interviews.

A key factor in engaging and retaining participants was engagement with their families. In a previous study, British Pakistani women [26] reported that a major barrier to social group participation was resistance from family members, particularly husbands. Hence; this intervention was presented to the families from the perspective of improving not only the health of the mother, but possibly also producing beneficial outcomes for the child. The acceptability of the intervention may have been enhanced by the availability of transport and free childcare. Earlier studies showed lack of transport to be a reason for drop outs [26, 49, 50]. Similarly, free crèche service was provided in a room adjacent to the PHP group intervention room, mothers were free to go and check their children as they pleased. The intervention was conducted during the school term to attract mothers with school-going children and to minimise dropouts. Reay and colleagues' pilot intervention study of a group interpersonal psychotherapy for postnatal depression reported similar findings [51].

A positive relationship with the group facilitators was found to be a vital factor for participation in the study. Chaudhry and colleagues also reported the importance of a healthy relationship between facilitator and mothers for successful intervention delivery [48]. Another key feature of this study is the cultural acceptability of the intervention and the facilitators' same ethnic background, which is reported to be important in previous studies as well [26, 52].

Women in this study did not receive the type of help they aspired for from the National Health Service (NHS). It is interesting to note that although the women described depression in physical terms, they provided no medical explanations to explain their condition rather all their explanations were psychosocial in nature. One of the research programs in Goa, India, looking at maternal health reported that although women described a number of somatic complaints, there was no 'denial' of their social and emotional contexts [53]. Regarding help for depression the findings suggest the need to develop culturally appropriate interventions and possibly starting with discussing somatic symptoms to cater for the needs of depressed British Pakistani women. At the end of the intervention, the participants in this study reported improvement in symptoms of depression. These findings are in line with Chaudhry et al. [48] who reported women in their study eagerly looked forward to attending the groups and used the expressions "mood became fresh" and "forgot our problems" to describe their positive experience which also resulted in enhanced self-confidence.

Our study suggests that depression is perceived as a reaction to unfavourable life events with a psychosocial aetiology rather than a biomedical model. The perceived causes of depression are similar to previous studies in the UK and those reported from Pakistan [22, 54]. A study from the UK reported that Black women were more likely to seek help from spiritual sources for depression than white women and reported spirituality as a coping mechanism [55]. There is evidence from earlier studies that women who lacked social, emotional and/or practical support continued to experience depression [31, 56].

Similar to the finding of Reay and colleagues [51], this study also showed improvement in marital relationships which might be attributed to exercising greater control over emotions and developing a positive attitude. The majority of women attributed marital problems as a significant factor for their depression. It has been suggested that marital difficulties can even lead to self-harm and

Table 2 Median MSPSS Scores across Three Time-Points

Subscale	Baseline median score	EOI[a] Median Score	*p*-value for improvement from baseline to EOI	6-Month Median Score	*p*-value for improvement from baseline to 6-month follow-up
Family	15	20.5	0.005	20	0.016
Friends	13	21	0.009	20.5	0.005
Significant other	11.5	22	0.008	19.5	0.012
Total score	40.5	60.5	0.005	59.5	0.005

[a]*EOI- End of intervention - (3 months)*

suicide in South Asian women [57, 58]. These results warrant attention as some studies suggest that South Asian women have higher rates of suicide compared to White women living in the UK [54, 58], particularly those with an affective disorder [59].

We found British Pakistani mothers' conceptualisation of depression to be very useful in guiding the development of group psychological treatment for depression. A majority of the women in the study favoured group intervention to address social isolation some suggested if individual therapy was also made available to offer flexibility and to maximise participation. Counselling services were found to be helpful in terms of having, "Someone to talk to", but women favoured problem solving approaches for the treatment of depression. These women described a degree of disempowerment and asked about ways of improving their self-esteem and self-confidence. However, there are certain cultural issues we need to be aware of, though these women described the need to become more empowered; they wanted this within the domains of the Pakistani culture. The study suggests a need for culturally sensitive treatment as opposed to standard 'usual care'. The women described health professionals as "lacking in knowledge and understanding of the Pakistani culture" and not understanding the underlying root causes. In a healthcare setting this would imply that staff should be trained in cultural awareness so that the women are able to say what they are thinking without feeling they may not be understood. Recent reports indicate inequalities in maternal health and the need for tailored maternity services to improve access to care for women from ethnic minorities [60].

Limitations and future research

The major limitation of the study is small sample and the non-controlled pre-post feasibility study design. Another limitation of the study is the difficulty encountered with some of the outcome assessment tools. When using the Dyadic Adjustment Scale tool, the women were reluctant to share certain personal information about the nature of their relationships with their husbands. Most women in this study believed that the intimate nature of a marital relationship should not be discussed outside of the marital relationship. We didn't collect data on the number of mums taking the antidepressants at any stage during the intervention or by the end of the intervention. Also, we were unable to determine if the mothers had persistent PND depression or if it was relapse of PND.

In addition, the study took place in one geographical area in England; hence, these results may not be generalisable to other regions and populations. The participants were from a Pakistani background, so the results may not be applicable to the other ethnic groups. A further limitation is selection bias as the sample was selected from an earlier existing cohort of British Pakistani women who may be more motivated to participate in research compared to other women attending primary care centres. In addition to the issues mentioned above, there is a need for future trials to measure self-esteem. This emerged as an important aspect during the delivery of the intervention.

Despite the fact that it was a hard to reach population to work with, two-thirds of the sample completed the intervention (10/15) and remained in the study till the end of the intervention. This also provides an estimate in terms of recruitment for future trials that a third of the participants may drop out of such interventions.

Conclusions

This study provides preliminary evidence for the feasibility and acceptability of a CBT-based culturally-adapted group psychological intervention for British Pakistani mothers. The participants found the culturally relevant psychological intervention acceptable and felt that the group sessions provided social support and helped to gain self-confidence. The participants reported that a more directive and problem focussed approach helped them to develop skills such as assertiveness, relaxation, and anger management. Reduction in depression and improvement in marital relationships, social support and overall health status mothers were noted but findings are limited due to the small sample size and no control group.

Abbreviations

CA-CBT: Culturally Adapted Cognitive Behaviour Therapy; CBT: Cognitive Behaviour Therapy; CISR: Clinical Interview Schedule – Revised; DAS: The Dyadic Adjustment Scale; EPDS: Edinburgh Postnatal Depression Scale; GP: General Physician; IPT: Interpersonal Psychotherapy; MSPSS: Multidimensional Scale of Perceived Social Support; PHP: Positive Health Programme; PND: Post-natal Depression; TAU: Treatment as Usual

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We declare that this manuscript hasn't been published in another journal. However, its poster was presented and its abstract was published in a conference [61].

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Availability of data and materials

Supporting data can be accessed by contacting the corresponding author.

Authors' contributions

SK. This was the PhD project of SK. She designed the study, delivered the intervention and did analysis and interpretation of the study. KL. KL was the advisor of SK in her PhD. She helped in designing the study and interpretation of the study. FL helped in analysis and interpretation of data. YM helped in analysis and interpretation of data. SS helped in structuring and writing the first draft of the manuscript. BT helped in study design and data analysis. NH was the main supervisor of SK in her PhD. He helped in designing the study, data analysis and interpretation of the data. All the authors contributed to writing the manuscript and have read and approved the final manuscript.

Ethics approval and consent to participate

"The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, and its most recent revision". The study was approved by both, the Local Research Ethics Committee and the University of Manchester (Registration number 10/H1005/62). The women were approached from October 2008 to February 2009, after obtaining written informed consent.

Consent for publication

The participants were aware that this piece of work is going to be published and provided written informed consent.

Competing interests

The authors declare that they have no competing interests.

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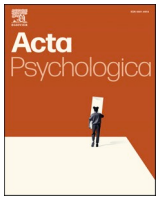

Exploratory RCT of a group psychological intervention for postnatal depression in British mothers of South Asian origin – ROSHNI-D

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ABSTRACT

Background: Postnatal depression (PND) is a global public health problem. There is a high prevalence of PND amongst ethnic minority women and major ethnic inequalities in mental health care in the U.K. Language and cultural barriers pose a significant challenge for access to timely treatment and interventions for British South Asian (BSA) women with PND.

Methods: The study, carried out in Manchester and Lancashire, England, was a two-arm single-blind exploratory randomised controlled trial. BSA women ($N = 83$) having a baby <12 months were randomised either to the group receiving the culturally adapted Positive Health Programme (PHP) ($n = 42$) or to the group receiving treatment as usual (TAU) ($n = 41$). Follow-up assessments were at 3 months (end of intervention) and 6 months after randomisation.

Results: Using an intention to treat analysis, there was no significant difference between PHP intervention and TAU groups in depression measured using Hamilton Depression Rating Scale both at 3 and 6 months follow up. Using modified intention to treat analysis, women who attended four or more sessions showed significant reduction in depression in the PHP group compared to the TAU group and the greater number of sessions attended was associated with greater reductions in depression scores.

Limitations: The sample was relatively small and the study was conducted in one geographical area in Northwest England; hence, these results may not be generalizable to other regions and populations.

Conclusion: The recruitment and trial retention figures highlighted the ability of the research team to engage with BSA women, having implications in planning services for this group.

Trial registration: Clinicaltrials.gov NCT01838889.

1. Introduction

Postnatal depression (PND) is a significant public health concern and even though the burden of postnatal depression is high, it is often under diagnosed and, therefore, under treated (Wan Mohamed Radzi et al., 2021). PND, which can range from low mood to psychosis, affects nearly 10 % to 15 % women during childbearing age (Langan & Goodbred, 2016) and, if left untreated, its impact goes beyond the mother and include developmental delays at one year of age, more frequent illnesses for the baby, failure to thrive, and impaired mother baby interactions

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(Dadi et al., 2020). Long-term implications for children having mothers with PND include insecure attachment bonds and social difficulties with peers (Glasheen et al., 2010). Consequently, PND affects not only the child and the family but also comes at an immense cost and resource burden on the healthcare system (Bauer et al., 2022).

The experience of PND is different across cultures and countries (Arifin et al., 2018). The UK is a diverse nation and is increasingly being represented by individuals coming from different countries and ethnicities with heterogeneous cultures, religions, and languages (Sihre et al., 2019). The British South Asian (BSA) population mainly comprising of women from Pakistan, India, and Bangladesh is the largest and fastest growing minority ethnic group (Census, 2021). Literature suggests BSA women have high rates of PND (Husain et al., 2012; Sihre et al., 2019). This disparity may be due to social isolation, financial problems, discrimination, deprivation, being a migrant and most importantly inequity in access and utilization of health care (Latif, 2014). BSA women are often considered to be 'difficult to reach' due to language and a lack of understanding of culture (Masood et al., 2015).

Postnatal depression is a preventable and treatable condition but can be challenging as nursing mothers are often reluctant to take medications and lack knowledge about psychological treatments available for postnatal depression (Howard & Khalifeh, 2020). The Saving Lives, Improving Mothers' Care report (Knight et al., 2015) for the period 2011–13, revealed that mental health problems were the cause of approximately one-quarter of all maternal deaths between 6 weeks and 1 year after childbirth, and that one in seven of those women had died by suicide. The report further suggests that in approximately 40 % of cases, if there was better health care, the outcomes could have been different. It has been reported that majority of the women do not access appropriate mental health support due to lack of awareness, family pressures, cultural differences, language and communication barriers, hence the women often suffer in silence (Nilaweera et al., 2014; Sihre et al., 2019). When considering interventions that work best for women from ethnic minorities, social isolation, loneliness and lack of support are important elements that need to be included in interventions (Husain et al., 2012; Masood et al., 2015).

The National Institute for Health and Care Excellence (NICE, 2018) guidance considers both Interpersonal Psychotherapy (IPT) and Cognitive Behavioural Therapy (CBT) as the most effective evidence-based interventions to treat PND. However, despite the Improving

Access to Psychological Therapies (IAPT) initiative, access to psychological interventions remains limited due to non-availability of therapists (Department of Health, 2014). Systematic reviews (Okumura & Ichikura, 2014; Scope et al., 2013) demonstrate the potential role of group CBT, as an alternate solution to access barriers by utilising an approach where a single therapist offers CBT to a group of mothers and women can speak openly and honestly about their feelings. There is limited evidence for the effectiveness of this approach in ethnic minority women and requires further research. NICE (2011) guidelines emphasize the need to improve access to care for ethnic minorities and tailor health services to make them culturally sensitive. Therefore, in this exploratory trial, ROSHNI-D (*Roshni* means light in Urdu/Hindi), we tested feasibility, acceptability and the efficacy of a culturally sensitive group CBT intervention, the Positive Health Programme (PHP) (Khan et al., 2019) in BSA women with PND and compared it to a routine treatment group.

2. Method

2.1. Trial design

The study was a two-arm exploratory single-blind randomised controlled design. Women were randomised either to the group receiving the culturally adapted psychological intervention, Positive Health Program (PHP) or to the group receiving treatment as usual (TAU). The follow-up assessments were completed at 3 months (end of intervention) and 6 months (post randomisation).

2.2. Sample size

Sample size was based on the assumption that a reduction in Hamilton Rating Scale for Depression (HDRS) (Hamilton, 1960) of 4 points would be of clinical significance (based on expert consensus) and would be feasible to achieve considering a similar reduction in HDRS in a PND study in South Asia (Rahman et al., 2008). Using the mean HDRS score of 22 and standard deviation 4 estimated from our preliminary work (Khan et al., 2019), the proposed study should have 80 % power to detect a reduction in mean HRSD in the intervention group of 4 points (i.e. from 22 to 18), in a two-tailed *t*-test with 5 % significance level, if complete follow up data were obtained on 20 patients in each group. This represents an effect size of 0.9, which is large. This estimate was based on similar work on psychosocial interventions conducted in South Asia (Rahman et al., 2008). We estimated that approximately one-third of the patients would drop out during the study and aimed to recruit 32 patients in each group.

2.3. Study participants

2.3.1. Setting

Recruitment took place in areas with high British South Asian ethnic density in Manchester and Lancashire. Potential participants were sent a letter from the General Physician (GP) at 6 weeks postnatal informing them about the trial, inviting their participation and requesting written informed consent. The letter enclosed an Edinburgh Postnatal Depression Scale (EPDS) (Cox et al., 1987; Husain et al., 2014) and Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001) for completion and return in a pre-paid envelope. In addition, potential study participants were identified using GP Practice-based electronic case records. Practice staff and/or Clinical Studies Officers (CSO) from the Primary Care Network carried out the search. The search criterion was filtered to identify South Asian mothers having a baby $<$12 months old. With the G.P.s' permission, identified mothers were contacted directly by phone via the practice or in person, in both cases by a CSO/practice staff member along with a bilingual Research Assistant. Female multilingual researchers also recruited participants from children centres, community centres, baby clinics, baby weight appointments and immunisation clinics. Other promotional methods included display of posters in community centres, and advertising via ethnic radio and T.V. channels.

2.3.2. Inclusion criteria

Self-ascribed British South Asian (BSA) women (Indian, Pakistani or Bangladeshi) meeting the International Classification of Diseases and Related Health Problems (ICD-10) depression criteria (WHO, 1993), aged 16 years or above, and having a child up to 12 months of age were invited to participate.

2.3.3. Exclusion criteria

Women who were diagnosed with severe physical or learning disability that would prevent participation in the trial, postpartum psychosis or other psychoses, severe depression, or were actively suicidal.

2.3.4. Recruitment and randomisation

Written informed consent was obtained from all mothers. All women who scored $\geq$12 on the EPDS (Cox et al., 1987) were invited for a diagnostic interview using the Clinical Interview Schedule - Revised (CIS-R) (Lewis et al., 1992). The CIS-R is a fully structured interview in order to increase standardisation and enhance suitability for use by trained lay interviewers in a primary care research setting (Lewis et al., 1992). All consenting women were administered the (CIS-R) to confirm the ICD-10 diagnosis of depression (WHO, 1993). Women who fulfilled the inclusion criteria were then asked to provide a second written

consent for randomisation. Consenting eligible participants were randomised via an independent remote telephone randomisation service based at Manchester Clinical Trials Unit (CTU). The randomisation was stratified by centre. Ethics approval was obtained from the North West Research Ethics Committee (10/H1005/62). The outcome assessors were kept blind to the participant's allocation. All efforts were made to ensure that the period between baseline assessment and randomisation was no longer than 4–6 weeks. The G.P. was informed about the patient's participation in the trial and treatment allocation by a letter, which was to be kept with the participant's medical notes.

2.4. Intervention AND TREATMENT AS USUAL

2.4.1. Treatment as usual

Treatment as usual (TAU) consisted of routine assessment and management as usually conducted by general practices. The G.P. discussed the most suitable options with the participant depending on the severity of the depression. The three main types of treatments offered were self-help strategies, therapy (IAPT services), and medications.

2.4.2. Intervention - positive health program

Previous work has highlighted the importance of culturally adapting Cognitive Behaviour Therapy (CBT) for it be effective amongst South Asian population (Naeem, 2019). Sobia Khan developed the Positive Health Program (PHP) as part of a PhD project and the intervention is based on CBT principles (Khan et al., 2019). The cultural adaptation of the manual-based group CBT intervention, described elsewhere (Khan et al., 2019; Masood et al., 2015) consists of 12 sessions completed over 3 months. The 12 sessions were delivered weekly. Each session lasted approximately 90 min on a specific day over 3 months at the local Sure Start Children's centre.

Group sizes were between 10 and 14 participants randomised to each group. A pair of ethnically matched female facilitators who delivered the sessions in both English and the participants' preferred language (English, Urdu, Bengali or Gujarati) led the sessions. The facilitators, National Health Service (NHS) band 4–6 mental health researchers, had backgrounds in psychology, social sciences, or related fields. They received training in the PHP delivery, group-facilitating skills and were supervised by an expert CBT therapist (KL) and psychiatrists (NC and NH). Supervision occurred fortnightly and additional supervision was available as required. One session of each group was observed by supervisors as part of fidelity checks.

The sessions covered a variety of topics including religion, spirituality, understanding and managing self-esteem. The session breakup is described below.

Week 1–11

- Reminder on ground rules (confidentiality and respect for fellow group members)
- Review of each participant's goal from the previous week
- Session allocation for the week (e.g. managing self-esteem in week 3). Each session included examples from vignettes or women could discuss their personal examples related to the session.
- Closing of the session by resetting the goals for the week followed by a light lunch.

Week 12

- Final goal setting for the future
- Farewell party and certificates for completing the PHP intervention.

Travel costs and participant time were reimbursed; crèche services and food were provided at each session. The facilitators illustrated key concepts by using flip charts, discussions, and group activities. They took weekly notes on the content of the sessions and participant's progress. All participants were reminded by phone, a day before the session and all non-attenders were contacted later to encourage further participation. All facilitators were Psychology graduates, they received training in PHP delivery, group facilitating skills and were supervised by an expert CBT therapist (KL) and psychiatrists (NC and NH). Overall, there were 4 positive health intervention groups, and each group was led in pairs by multi-lingual facilitators.

2.5. Outcome measures

Assessments were carried out at baseline, 3 months (end of intervention) and 6 months post randomisation (Appendix 1). All participant information and study assessments were available in relevant south Asian languages developed using our guidelines (Rahman et al., 2008).

2.5.1. Steps taken to protect against bias

It is not possible to blind participating mothers, their GPs, or practice health visitors to treatment group. An outcome assessor (OA) unaware of treatment allocation collected the outcome measures and the self-reporting measure (EPDS). We minimised selection bias by recruiting mothers from two different geographical areas in the North West region and by keeping exclusion criteria to a minimum

2.6. Screening assessments

2.6.1. The Edinburgh Postnatal Depression Scale (EPDS)

EPDS was completed at the initial screening stage for depression. It is a 10-item questionnaire, and total score was calculated by sum of score of all items. A score of $\geq$12, the most commonly used cut-off was used to distinguish cases from non-cases (Cox et al., 1987). EPDS has previously been used on Pakistanis in U.K. and is available in English and Urdu (Husain et al., 2014).

2.6.2. Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a valid measure of severity of depression, a nine items questionnaire that records responses from 0 (not at all) to 3 (nearly every day). The score of each item is added up to measure severity (Kroenke et al., 2001). Demographic and socio-economic data was collected as well.

2.7. Baseline assessments

All assessment questionnaires were also available in Urdu, Hindi, Gujarati and Bengali. The completion of the questionnaires took no >60–90 min at any one time. All these measures have been used in our previous research in similar population and no report of discomfort or harm has been reported (Khan et al., 2019).

2.8. Clinical Interview Schedule - Revised (CIS-R) (Lewis et al., 1992).

2.8.1. Hamilton Rating Scale for Depression (HRSD)

The symptoms of depression as assessed with the 21-item HRSD (Hamilton, 1960). HRSD has been reported to give valid and reliable results in the primary care setting. We have used the HRSD in Manchester with British women of Pakistani origin (Chaudhry et al., 2009) and also in Pakistan (Husain et al., 2014).

2.8.2. The Parenting Stress Index (Short Form)

The Parenting Stress Index (PSI) yields a Total Stress Score and scale scores for both child and parent characteristics, which identify sources of stress within the family. The PSI has been empirically validated with populations as diverse as Chinese, Portuguese, which demonstrates comparable statistical characteristics to those reported in the PSI Manual. The PSI therefore maintains its validity with diverse non-English-speaking cultures. All 36 items on the PSI Short Form (PSI/SF) (Abidin, 2012; Barroso et al., 2016; Holly et al., 2019) are contained on the Long Form with identical wording and are written at a 5th-grade reading level.

2.8.3. Multidimensional scale of perceived social support (MSPSS)

The MSPSS is a 12-item scale that uses a 7-point response format. It assesses perceived support from each of the three sources: family, friends and a significant other. Its validity and reliability have been studied in several countries including Pakistan, which have all reported excellent psychometric properties (Akhtar et al., 2010; Eker et al., 2000,).

2.8.4. Verona Service Satisfaction Scale (Ruggeri & Dall'Agnola, 1993)

Patient satisfaction with treatment was measured with the abridged version. Six items were extracted from the scale and tailored specifically for this psychological intervention.

2.8.5. The Dyadic Adjustment Scale (DAS) (Spanier, 1976)

A 32 item self-report measure of relationship adjustment was used to measure relationship with husband/partner.

2.9. Statistical analysis

Firstly, an intention to treat analysis was carried out, using all available follow up data in the randomisation groups, regardless of whether patients attended therapy sessions. Mean and standard deviation scores for age and all continuous measures at baseline and two follow-ups are presented. The two treatment groups were compared using *t*-tests for age and baseline scores and using analysis of covariance with baseline score as a covariate for follow up scores. Differences between group means are presented with 95 % confidence intervals, and effect sizes for each comparison. Spearman's correlation coefficient was used to measure associations between changes in the severity of depression and changes in age and secondary measures. We also carried out a further analysis looking at mothers who attended 4 or more sessions. All analyses were carried out using SPSS version 20.

3. Results

A total of 83 women consented to participate, of which 42 were randomised to the Intervention group (Table 1). The recruitment (n = 560) and retention of participants (80 % at end of intervention and 76 % at 6 months) highlight the ability of the research team to engage with this population. There were no significant differences in age, or any of the questionnaire scores at baseline, although the PHQ-9 scores were substantially higher in the PHP intervention than in the TAU group, and almost statistically significant. There was no significant difference between PHP intervention and TAU groups for any of the scores at either follow up. The effect size was 0.10 and 0.06 at the two-follow ups for EPDS, and 0.13 and 0.16 for HDRS, which are all much smaller than anticipated. However, they are larger for some of the secondary measures, such as MSPSS at second follow up (0.38) and PSI at second follow up (0.32).

Of the 66 patients who were depressed at baseline using EPDS score 12 or more, there was no significant difference between groups at either follow up on the numbers depressed. At 3-month follow up, 8 out of 26 PHP intervention and 9 out of 27 TAU participants were still depressed, and at 6 months follow up, 11 out of 26 intervention and 10 out of 25 control participants were still depressed. The analyses were repeated for the subgroup of 33 patients in each group who had an EPDS score of 12 or more at baseline. The PHP intervention group had significantly higher baseline EPDS scores than the TAU (mean = 18.7, sd = 4.1 vs. mean = 16.5, sd = 3.3, $t = 2.4$, $p = 0.018$), and they also had significantly higher baseline PHQ-9 scores than the TAU (mean = 12.7, sd = 6.4 vs. mean = 9.0, sd = 5.7, t = 2.4, $p = 0.021$), but there were no other baseline differences between the groups. There were no significant differences between the two groups for any of the scores at either follow up.

Following the initial intention to treat analysis, a further analysis based on PHP group attendance was conducted. After developing consensus with our colleagues, completers were defined as those participants who had attended 4 or more sessions. Fifteen of the 42 participants in the PHP group did not attend any sessions, while the remaining 27 patients attended at least 4 sessions. Overall, the mean number of sessions attended was 6.6 (sd = 5.2, range 0–12). Spearman's correlation coefficient between the number of sessions attended and reduction in Hamilton score from baseline to 3 month follow up was

Table 1
Mean scores for age, EPDS, DAS, MSPSS, PSI, PHQ-9, Hamilton, EQ-5D total and HOME at baseline and 2 follow ups according to treatment group.

	Intervention Mean (sd) n	Control Mean (sd) n	Difference between means (95 % CI)	*p*-Value	Effect size
Age	30.4 (6.0) 42	30.1 (5.4) 39	−2.1 to 2.9	0.77	
EPDS					
Baseline	16.3 (6.0) 42	14.9 (4.6) 41	−0.9 to 3.8	0.23	
Follow-up 1	7.9 (5.9) 32	8.2 (6.3) 32	−3.6 to 2.5	0.70	0.10
Follow-up 2	9.4 (6.8) 31	9.2 (6.5) 31	−3.8 to 3.0	0.81	0.06
DAS					
Baseline	56.1 (30.3) 42	60.7 (37.2) 41	−19.4 to 10.2	0.54	
Follow-up 1	74.7 (23.3) 31	76.1 (19.6) 29	−11.1 to 11.2	0.99	0.004
Follow-up 2	71.5 (21.3) 25	77.3 (19.4) 29	−14.2 to 7.7	0.56	0.16
MSPSS					
Baseline	42.0 (16.9) 42	43.5 (23.2) 41	−10.4 to 7.3	0.73	
Follow-up 1	55.5 (17.7) 33	59.3 (15.1) 30	−10.7 to 4.9	0.46	0.18
Follow-up 2	53.3 (13.4) 28	58.8 (15.1) 28	−13.1 to 2.3	0.16	0.38
PSI					
Baseline	62.1 (45.7) 42	50.7 (45.8) 41	−8.5 to 31.5	0.26	
Follow-up 1	64.4 (19.9) 30	63.7 (22.9) 32	−10.9 to 10.7	0.98	0.006
Follow-up 2	73.6 (21.5) 27	66.6 (18.5) 28	−4.5 to 17.3	0.25	0.32
PHQ-9					
Baseline	11.0 (6.7) 38	8.1 (5.7) 37	−0.004 to 5.7	0.050	
Follow-up 1	4.9 (4.6) 30	5.1 (4.5) 32	−3.1 to 1.6	0.52	0.17
Follow-up 2	6.2 (4.4) 28	4.2 (5.0) 30	−1.4 to 3.8	0.35	0.26
Hamilton					
Baseline	14.8 (5.7) 42	13.0 (6.1) 38	−0.8 to 4.5	0.17	
Follow-up 1	5.9 (5.6) 32	6.0 (5.7) 32	−3.6 to 2.1	0.60	0.13
Follow-up 2	9.0 (5.5) 28	7.2 (7.3) 31	−2.3 to 4.4	0.53	0.16
EQ-5D total					
Baseline	7.2 (1.5) 42	7.4 (2.3) 38	−1.0 to 0.7	0.72	
Follow-up 1	5.5 (0.8) 32	5.9 (1.2) 32	−0.96 to 0.07	0.090	0.44
Follow-up 2	6.0 (1.4) 28	5.8 (1.7) 31	−0.67 to 0.97	0.71	0.10
HOME					
Baseline	26.5 (6.7) 22	29.7 (9.3) 23	−8.1 to 1.6	0.19	
Follow-up 1	27.6 (7.3) 16	29.5 (6.2) 16	−5.9 to 5.0	0.87	0.07
Follow-up 2	30.2 (8.0) 21	29.5 (8.2) 26	−9.4 to 4.2	0.43	0.32

Comparisons between randomisation groups made by *t*-test at baseline, and by analysis of covariance at follow ups with baseline score as covariate.
The effect sizes have been calculated using the adjusted difference between groups means using ANCOVA and the average sd from the table above.

0.35, $p = 0.048$, with greater reductions in Hamilton score being associated with more sessions attended.

4. Discussion

This exploratory RCT was the first in the U.K. designed to meet the psychological needs of BSA women with PND. BSA women are often excluded from psychological therapies because of gender, language or cultural differences. Culturally adapted, evidence based preventive programmes to support maternal mental health problems are showing potential, though require further work (Ward et al., 2022). Through this exploratory trial, we were, firstly, able to demonstrate the feasibility of the trial procedures: we met our anticipated recruitment targets, the mothers were successfully randomised and retained in both arms, and no trial related adverse events were reported. Secondly, even though we were not able to provide evidence on the efficacy of the intervention, no significant difference between PHP intervention and TAU groups for depression at both 3 and 6 months follow-ups were reported. The present study can be considered an important step to improve current knowledge on conducting research with a hard to engage group who is at an elevated risk of PND. Thirdly, we also tested our ability to run a series of group sessions at multiple sites, in the local Sure Start children's centres in Manchester and East Lancashire.

A systematic review of guidance on exploratory studies to decide whether and how to proceed with full-scale evaluations of public health interventions (Hallingberg et al., 2018) suggests randomisation within an exploratory study as necessary for examining feasibility of recruitment. We were able to recruit ($n = 560$) and randomise 42 mothers in the intervention group and 41 in TAU. Our exploratory trial also adhered to all key aspects considered crucial for conducting feasibility trials as proposed by Thabane et al. (2010) and these included: assessing the safety of interventions; assessing recruitment potential; assessing the feasibility of coordination for multi-centre trials; and increasing clinical experience with the intervention for future large scale trials. All efforts were also made to ensure that the duration between baseline and randomisation matched the average wait time for therapy of 6–8 weeks. There was no difference in this approach between the two arms.

Considering this is a hard to engage population, the trial retention figs. (76 %) highlight the ability of the research team to successfully respond to the needs of the mothers. Previous studies on group interventions with British Pakistani mothers have documented 66 % (Khan et al., 2019) and 50 % (Chaudhry et al., 2009) respectively as trial retention figures. Several factors such as using native language, culturally aware therapists and facilitators, childcare facilities and transport assistance helped us to better engage and retain participants in our exploratory trial. These factors were identified in earlier studies conducted with British South Asian populations (Gater et al., 2009; Mir et al., 2015; Khan et al., 2019).

Qualitative research is encouraged for assessment of intervention acceptability, its implementation, to examine retention rates, and reasons for drop out (Eldridge et al., 2016; O'Cathain et al., 2015). We conducted in-depth qualitative interviews ($n = 17$) with mothers who attended the group intervention and the responses suggested that the culturally adapted PHP was acceptable to the service users. Cultural beliefs, values and traditions are considered essential in intervention planning and execution for maternal depression (Jidong et al., 2021). The participants in our study also felt an overall positive change in their attitudes, behaviour and confidence level after attending the sessions (Masood et al., 2015). Similar findings have been reported by Khan et al. (2019).

A modified analysis of participants found that greater number of sessions attended was associated with significantly greater reductions in depression scores both using interviewer administered HDRS and self-reported EPDS scores. Similar results have been documented in a recent study on lower versus higher frequency of sessions in mental health care (Tiemens et al., 2019) and the findings suggested that both improvement and recovery were associated with a higher frequency of sessions during the first three months of treatment. Forde et al. (2005) report that for reducing depression, attending 6–8 sessions offers more benefit than attending 1–5 sessions.

We benefitted immensely from the involvement of service users and the public. One of the main outcomes of the trial was that we were able to enhance awareness about mental health problems in this underrepresented population. We also ensured extensive patient and public involvement throughout the trial, including their input in refinement of the psychological intervention and the interpretation of the research findings. Several community events were held which offered Patient and Public Involvement (PPI) opportunities and we held regular research meetings at various clinics across Manchester and Lancashire to discuss the trial, which promoted the interest of the service users. Some of the participants were invited to attend our annual 2-day qualitative research methods course at the University of Manchester to develop skills to assist in interpreting qualitative data. The availability of a culturally acceptable intervention of proven effectiveness is the next critical first step in improving access. Further to this pilot trial, our PHP intervention is currently being evaluated in a NIHR funded multi centre RCT "ROSHNI-2" (ISRCTN10697380).

5. Strengths and limitations

One of the major strengths of our study was that the team was able to reach out to a population which typically has trust deficit and reservations to access the health care system for postnatal depressed British South Asian women (BSA) and carry out the study with bilingual researchers which allowed participants to complete the intervention in their preferred language. Our strength, which has implications for service delivery, was also in our ability to run multi-site interventions for several groups across Manchester and East Lancashire area. The project has also provided a good example of collaboration with psychological intervention delivery through established Sure Start centres and multidisciplinary working including primary care, IAPT, community workers and health visitors.

There were a number of limitations that should be considered. The sample was relatively small. Further, the study took place in one geographical area in England; hence, these results may not be generalizable to other regions and populations. Further, the geographical proximity of many of the participants, both in the PHP intervention and TAU groups, can lead to the assumption that they were acquainted with each other with a possibility of sharing their experiences of participation in the intervention as well. Potential contamination therefore cannot be excluded. Another limitation of this study is the that we did not have documented reasons from mothers who dropped out and did not attend any of the sessions as this information would have helped us better understand the acceptability of the PHP intervention and the constraints mothers face in attending such sessions.

Our exploratory randomised controlled trial (RCT) has limitations regarding internal validity due to the discrepancy between estimated large effect size, which informed our sample size calculations, and the observed low effect size. This discrepancy suggests the study is underpowered, potentially leading to underestimation of the intervention's true effects, increasing the risk of Type II error, and thus compromising the internal validity. Additionally, the small sample size could have increased the impact of potential confounding variables, further limiting the findings of the study. While these issues are present, the value of this study as an exploratory RCT should not be underestimated. Exploratory trials are crucial steppingstones towards informing methodologies in future research. They can offer initial insights into an intervention's effects, help identify potential confounding variables, and guide more accurate effect size predictions for definitive studies. Therefore, despite our observed low effect size, our study's findings remain a significant contribution to the larger body of evidence, paving the way for adequately powered and methodologically sound future RCTs.

6. Conclusion

To our knowledge, this is one of the first exploratory RCT designed to examine the psychological needs of BSA women with PND. We have been able to assess the feasibility and acceptability of working with BSA women with postnatal depression, willingness for the participants to be randomised and the preliminary data to calculate sample size and power calculations for a larger definitive trial - ROSHNI-2 (Husain et al., 2022).

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CRediT authorship contribution statement

N.H. led overall project development and supervision and contributed to the manuscript writing/editing supported by FL. KL was responsible for intervention training, development and supervision. FL and AS were researchers on the study and responsible for recruitment and day to day study delivery. DS, NZ, AI have contributed to manuscript write up and editing. BT was responsible for the analysis and write up of results. WW, NC were site leads and coordinated study delivery and supervision of research staff. AB was GP at a leading recruiting practice and provided support in local study delivery. All authors read and approved the final version.

Declaration of competing interest

NH is a past Trustee of Manchester Global Foundation (MGF), The Pakistan Institute of Living and Learning (PILL), Abaseen Foundation U. K. and Lancashire Mind U.K. He is executive member of the Academic Faculty at the Royal College of Psychiatrists, London. He is a NIHR Senior Investigator. In the last five years he has attended educational events organized by various pharmaceutical industries.

Data availability

Data will be made available on request.

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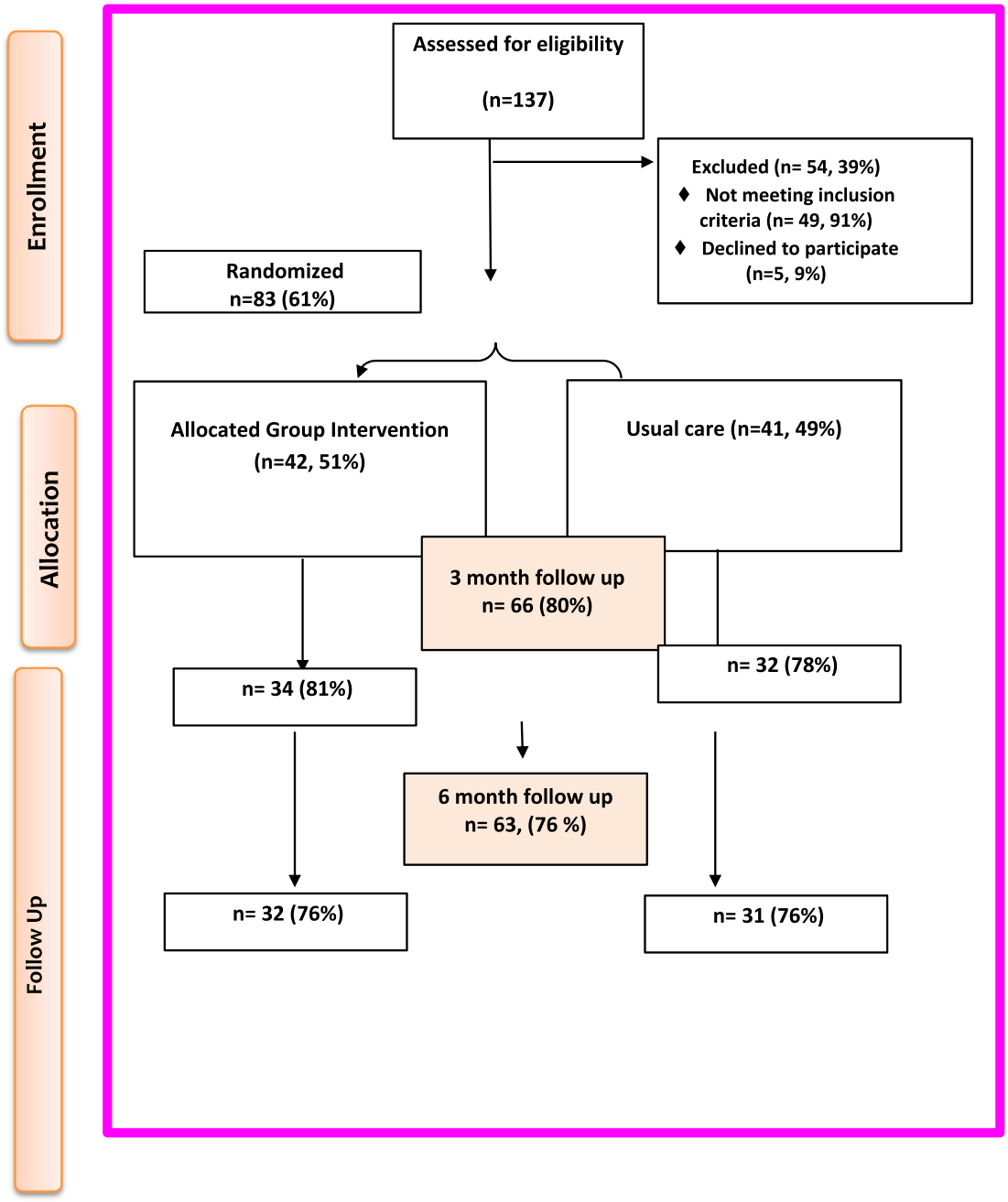
Appendix 1. ROSHNI-D consort flow diagram



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Group psychological intervention for postnatal depression: a nested qualitative study with British South Asian women

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Abstract

Background: Postnatal depression affects 10–15 % of all mothers in Western societies and remains a major public health concern for women from diverse cultures. British Pakistani and Indian women have a higher prevalence of depression in comparison to their white counterparts. Research has shown that culturally adapted interventions using Cognitive Behavioural Therapy (CBT) may be acceptable and may help to address the needs of this population. The aim of this study was to assess the acceptability and overall experience of the Positive Health Programme by British South Asian mothers.

Methods: This was a nested qualitative study, part of an exploratory randomized controlled trial (RCT) conducted to test the feasibility and acceptability of a culturally-adapted intervention (Positive Health Programme or PHP) for postnatal depression in British South Asian women. In-depth interviews ($N = 17$) were conducted to determine the views of the participants on the feasibility and acceptability of the intervention.

Results: The participants found the intervention acceptable and experienced an overall positive change in their attitudes, behaviour, and increased self-confidence.

Conclusions: The findings suggest that the culturally adapted Positive Health Programme is acceptable to British South Asian women. These results support that culturally sensitive interventions may lead to better health outcomes and overall satisfaction.

Trial registration: Protocol registered on Clinicaltrials.gov NCT01838889

Keywords: Cognitive behavioural therapy, British South Asian, Postnatal depression, Cultural adaptation

Background

Postnatal depression affects approximately 8.5–11.0 % of all mothers in Western societies [1, 2]. The prevalence of perinatal depression is higher among mothers from certain ethnic minority groups [3]. This indicates ethnicity to be a significant risk factor for developing postnatal depression. Ethnicity has also been reported to be linked to poor health outcomes for both ethnic minority mothers and their infants, as reflected in higher rates of infant and maternal mortality and morbidity and lower birth-weight [4]. Part of this risk lies in the interaction of economic disadvantage with ethnic minority grouping.

Postnatal depression is a treatable disorder [5]. Antidepressants are effective, but new mothers are reluctant to take such medications whilst nursing [6]. Among psychotherapeutic interventions, Interpersonal Psychotherapy (IPT) and Cognitive Behavioural Therapy (CBT) have shown the most efficacy in the treatment of postnatal depression [6–8]. With regard to the postnatal treatment of British ethnic minority women, the National Institute of Clinical Excellence (NICE) [9] 2007 guidelines recommend that they should be provided with culturally sensitive information and treatment. However, we know from our earlier work [10, 11] that several barriers prevent

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access to appropriate mental health services for British South Asian women. Even where help is accessible it is not sensitive to the cultural needs of this population.

British South Asian women have higher birth rates compared to the majority white population and are considered 'difficult to reach' due to language and cultural barriers. Research [12, 13] indicates that British Pakistani women have high rates of postnatal depression, lack social support, experience interpersonal relationship problems [12] and linguistic and cultural barriers in accessing services [14]. Isolation and lack of social support are therefore important elements to be addressed in interventions. There is, however, little empirical evidence addressing the adaptation of evidence-based interventions to ensure their applicability to specific ethnic communities [15–18]. Recent studies evaluating a culturally-sensitive psychosocial group intervention for the treatment of depression in British Pakistani women reported an improvement in participants' self-confidence at the end of the intervention [11, 19]. Overall, the findings indicated that social groups which had taken into consideration the sociocultural needs of British Pakistani women experiencing depression were acceptable to them.

Despite the above research, there is a clear gap in evidence for informing culturally-sensitive interventions for maternal depression in British South Asian women [18–20]. This paper provides a qualitative evaluation of a psychosocial intervention called the Positive Health Programme (PHP), which was adapted for and offered to British South Asian women experiencing postnatal depression. The programme was designed to be delivered to groups of participants using the cognitive behavioural model [21]. The manual assisted programme, tailored to the cultural needs of British Pakistani women, was developed by our group and initially feasibility tested for a PhD project [22]. It consisted of 12 weekly group sessions delivered over 3 months. The manual is organized into 9 distinct sections.

The main trial

This paper describes the results of a post-intervention qualitative study as part of an exploratory randomized controlled trial conducted to test the feasibility and acceptability of a culturally-adapted intervention (Positive Health Programme or PHP) for postnatal depression in British South Asian women. The study was carried out across Manchester and Lancashire (UK). The recruitment (N = 615) and trial retention figures (70 %) highlight the ability of the research team to engage with this population. In the intention-to-treat analysis there was no significant difference between intervention and control groups for any of the depression scores at either follow-up. Following the initial analysis, another analysis was carried out based on attendance to the intervention. Completers were defined as those participants who had attended 4 or more sessions. Fifteen of the 42 patients in the intervention group did not attend any of the therapy sessions, while the remaining 27 patients attended at least 4 sessions. Overall, the mean number of sessions attended was 6.6 (SD = 5.2). The Spearman's correlation coefficient between the number of sessions attended and reduction in the Hamilton score from baseline to follow-up 1 was 0.35 (p = 0.048), with greater reductions in the Hamilton score being associated with more sessions attended. Correlations between changes from baseline to follow-ups in the other variables ranged from −0.20 for EPDS at the second follow-up.

This paper describes the qualitative phase of the trial and explores the participants' experiences of receiving the PHP.

Aims

To assess the acceptability and overall experience of the Positive Health Programme by British South Asian mothers.

Objectives

1. To identify the barriers faced by the British South Asian women in accessing the intervention.
2. To identify factors which facilitated participants' engagement with the PHP.

Methods

This study aims to explore a wide range of views and experiences of British South Asian women which quantitative methods do not often allow to be explored in detail [23]. In contrast, qualitative methods for data collection are sensitive to the unique personal experiences, perceptions, beliefs, and meanings related to individuals and therefore believed to be the most appropriate method to be employed within this study [24]. Qualitative analysis also offers an accessible and theoretically flexible approach to analysing qualitative data [24]. One of the strengths of this approach is that it enables the researcher to focus on identifying themes and patterns of behaviours [25].

Recruitment

A total of 83 women with a confirmed diagnosis of depression using the Clinical Interview Schedule-Revised (CISR) interview [26] took part in the RCT. These women were of South Asian origin as defined by the Office of National Statistics (ONS) (ONS is the recognised national statistical institute for the UK providing official statistics), over the age of 16 years, and living with their babies. The PHP programme was offered to 42 British South Asian women who were randomly allocated to the intervention arm of the randomised controlled trial (RCT). The women were recruited between 2012 and 2013 from multiple sites in

Manchester and Lancashire, including General Practices and Children Centres, and were organised into 4 groups for evaluation of the PHP. The programme was delivered at the local Sure Start children's centre over a 12-week period by trained research staff. Of the 42 women who were randomised to the PHP group intervention, 20 were randomly selected using the random number tables and were invited for qualitative interviews. A total of 20 women were contacted for obtaining informed consent, 17 agreed to take part, whilst three could not be contacted. Five of the participating women were from the Manchester intervention group and the remaining 12 were from the Lancashire intervention group. The interviews took place at the participants' homes as most did not have access to alternative child care arrangements.

Procedure

In-depth interviews were conducted with the participants using a topic guide. The topic guide for this study was developed and informed by both existing literature in this area and an earlier feasibility study [22]. The key areas explored were reasons for participation, barriers to receiving the intervention, and perception of the intervention process including participants' initial expectations and reflections. The interviews explored participants' views on how the PHP sessions took place, the format and frequency of the sessions, the characteristics of the facilitator, the use of handouts and other session materials, and the acceptability of the delivery of the intervention. Each interview lasted approximately 45 min and was conducted in the participant's preferred language; all the interviews were carried out in the Urdu language. Later these interviews were translated into English. The analysis and coding process was also carried out in English.

Ethics approval

The study was approved by the North West Research Ethics Committee (10/H1005/62).

Analysis

Interviews were transcribed verbatim, anonymised, and analysed using thematic analysis [27]. Thematic analysis is a flexible approach where, in contrast to other qualitative methods, the researcher is attached to a theoretical framework [28]. Thematic analysis is appropriate for use in a multi-method context where the qualitative element of enquiry is framed by prior work consistent with the present study which is embedded in a larger randomised controlled trial. The complete interview recordings were listened to and the corresponding transcripts were read over multiple times for familiarization [29]. A code book was maintained to keep the process of coding systematic and intact. Specific events, thoughts, and actions were coded or identified as themes on the basis of their ability to "capture something important in relation to the overall research question" ([27], p.82) by the researcher, YM. The researcher did not try to fit the codes into existing code frameworks. The coding process aimed to identify themes that were internally homogenous, externally homogenous, and had explanatory power. This involved an iterative process comparing themes against transcript data in order to ensure that the emerging structure of themes continued to be grounded only in the data set. Ultimately, the data collection process ended due to thematic saturation (where no additional themes were achieved) [28]. Participants' responses were first analysed on a semantic level, whilst the main themes were developed at the second stage, involving latent analysis of how coherently and adequately the themes represented the meaning of the data as a whole [27]. Themes and sub-themes were reviewed between the researcher (YM) and the supervisor (KL) before the analysis was finalized.

Results

A total of 17 women took part in the qualitative interviews; the age range was 20–45 years. The sample characteristics are described in Table 1.

Motivators to participate in the Positive Health Programme (PHP)

Most of the women stated overcoming depression through a better understanding of their mental health issues, enhancing their confidence, meeting other women in similar

Table 1 Sample characteristics of all participants (n = 17)

Participant	Age range	Generation	Ethnicity	Marital status
1	30–35	First	Pakistani	Married
2	25–30	Second	Pakistani	Married
3	20–25	First	Pakistani	Married
4	35–40	First	Pakistani	Married
5	20–25	Second	Pakistani	Married
6	30–35	Second	Pakistani	Married
7	35–40	Second	Indian	Married
8	25–30	Second	Bangladeshi	Married
9	40–45	First	Pakistani	Married
10	30–35	First	Pakistani	Married
11	40–45	Second	Pakistani	Married
12	25–30	First	Pakistan	Divorced
13	30–35	First	Indian	Married
14	30–35	First	Pakistani	Married
15	25–30	First	Pakistani	Married
10	30–35	First	Pakistani	Married
17	30–35	First	Pakistani	Married

situations, and sharing experiences as the major motivating factors for participation in the programme.

> Yes, definitely! I wanted to come out of depression and wanted to meet new people because to me loneliness was the main reason of my depression. And to me, if there are other women who are lonely, they should meet up and join these groups. Because of these you get to know about other people and their situations. (ID 3)

Barriers to attendance and commitment

The sessions were held during the mornings which most participants found convenient since it did not impact their daily chores. Furthermore they had the support of their family members.

> No, there was no issues, no problems. My husband is really supportive and he allowed me to go and join these groups. (ID 3)

However, a few participants mentioned restrictions from their husbands because they could not comprehend the need for the intervention. At times the husbands were not informed about the sessions or were not told of the nature of the sessions for fear they would not allow the participants to attend.

> My husband did not want me to go; he did not let me go anywhere. I had to look after my children, but he just wanted me to sit with him and talk to him. (ID 2)

> My husband didn't know that I was going to these classes. I used to be home before he came back from his work. (ID 9)

The participants considered the absence of childcare arrangements as a potential barrier to attending the sessions.

> And we were offered a crèche facility; I used to take him there; otherwise it would have been really difficult for me. (ID 13)

Most of the participants did not drive and relied on family members for transport arrangements to and from the centre. Having transport expenses paid by the programme was appreciated by all the participants because it reduced the burden of transportation expenses on the participants.

> Yes, there was the issue of travelling. I cannot drive and my husband was admitted to the hospital. But then they said they would pay me, so I continued with the classes. (ID 1)

Most of the participants reported difficulty in completing the between-session work due to excessive domestic responsibilities. However, all participants did realise that between-session work was important for improving their psychosocial well-being.

> The homework was useful but my children were young and I couldn't do that much. I tried but I could not do that much. (ID 11)

Understanding of cultural and linguistic needs

Group facilitators conducting the sessions were of South Asian origin which enabled them to communicate in the participants' first language (Urdu) resulting in increased group engagement and participation.

> She spoke in Urdu and I had no problems. If she had spoken in English then I might have had some problems and I would have not even attended. (ID 3)

Some of the participants expressed concerns over not being able to read the handouts due to lack of English reading skills. This resulted in their dependence on other group members and facilitators to understand the handout content. It was suggested that the handouts be translated into the participants' first language to make them useful for the readers.

> For me it was ok. I did not have any problem; but I feel for women who could not read English handouts need to be written in Urdu. These women felt that they were depending on us or the facilitator for guidance. (ID 4)

The participants appreciated the facilitator's knowledge and understanding of their socio-cultural dynamics which enabled the facilitators to relate to the participating women's culturally specific issues and address them in the sessions sensitively.

> Because she understood what we go through, how our culture is, and how our belief systems are. She could understand us better than anyone else. (ID 5)

Most importantly, facilitators' skills such as the ability to listen and empathise, encouraging and non-judgemental attitude were recognized as important, facilitating open and honest discussions within the groups.

> …the main thing is that she listened to all of us. There were times that we did not want to talk and we were shy or hesitant; but she was very encouraging. She made us feel that it is ok and we can open up. She gave me the courage to speak openly about my

feelings. She appreciated us all to be more involved and this made us open and be more communicative to others. (ID12)

Participation in group sessions

A group-based intervention was appreciated and supported by nearly all the participants. They felt that the group allowed them to share information, and understand and explore solutions to their problems from each other's perspectives. The mothers felt that the group was the only platform where they had an opportunity to express their emotions and feelings in a safe environment and this is something they are often not able to do with their own families.

… the best thing was I did not know anyone;. Sometimes you don't want to discuss your personal matters with people you know. (ID13)

However, some participants felt reluctant to disclose personal issues in group settings due to fear of breach of confidentiality. It was suggested by some of the participants to incorporate some individual sessions in between group sessions.

In individual sessions, one can talk about problems which can't be discussed in a group. And for groups we can share and learn from each other. (ID12)

Open discussions were nonetheless much favoured within the group as these offered flexibility along with giving the opportunity to practise assertiveness skills they had acquired during the sessions. Some participants preferred storytelling activities, which allowed them to talk about issues and explore solutions indirectly, without attracting attention.

I think open discussion was good and felt discussions helped in overcoming my anxieties and shyness. To me, these open discussions gave me the confidence to interact and overcome my depression. (ID8)

Feeling confident and empowered

All the sessions were found useful by the participants as they reported overall improved wellbeing. They felt better able to deal with their day-to-day tasks. They also reported enhanced self-esteem, being more proactive, and being able to manage stress more effectively. They also spoke about embracing and adopting a positive view of life.

I am more relaxed and confident. Earlier, I could not speak and even go out of my house; now I go out with my friends and feel that I can learn new things as well. (ID6)

Learning positive thinking strategies and coping skills, along with group participation and a good relationship with the facilitator were reported as the most important factors for facilitating change.

Um…it's the classes and the therapist. My life segments are still there but I have changed my thought process. I have a coping strategy for my problems. (ID10)

Most of the women reported being able to manage their everyday life more easily than before. The overall change was noted when dealing with children, family members, and oneself. Coping skills incorporated techniques for stress and time management as well as relaxation techniques.

Yes, it has. I am managing my family with less stress; I have realized and have gained the knowledge of overcoming my tension when I am dealing with my children and husband. I tell them I can do only so much at a time and they shouldn't be expecting a lot from me. (ID2)

Suggestions for improvement

A majority of the participants highlighted the need for such interventions to be ongoing as according to them psychosocial problems are deep-rooted and require much longer interventions.

Well, because it takes time to recover and then I might encounter some more issues in my life for which I might need guidance and assistance. You know, we are alone here; there is no one with whom to share and discuss our issues. (ID6)

Some participants suggested follow-up or 'top-up' sessions to motivate them to continue using the strategies learnt in the sessions and also as an opportunity to discuss additional issues and concerns with the facilitator.

Well, I thought the sessions went by too quickly and 12 weeks were not enough. I would have liked more sessions later because if something was missed or someone did not pick up something, at least they could have gone back and asked. (ID14)

One of the participants indicated health professionals' lack of awareness of issues specific to ethnic minority communities and suggested that professionals such as GPs and nurse practitioners should be given culture-specific training.

> Yes, what happened was, when I went to see my nurse um…they did not give me any direction where to go. I think GPs should be more involved, but these sessions were really good. (ID13)

Discussion

The findings of our study highlight the experiences and acceptability of a culturally-adapted intervention (PHP) by British South Asian women. The main reasons for participants to engage and participate in the PHP were to gain support and to improve their self esteem and well-being. These findings are in line with the Villegas & McKay [30] study where low self-esteem has been reported as a risk factor for developing postnatal depression. The perception of the group as a way of getting social support by most of the participants is consistent with the findings from a US-based study reporting women who continued to be depressed two years after giving birth as more likely to lack social support [31].

The participants in our study reported feeling positive after the PHP intervention, although some faced barriers from the family. A key factor in retaining women in the PHP intervention was engaging with their family members, which facilitated their attendance at the sessions. A study with Pakistani women with postnatal depression living in Pakistan [32] reported that the intervention, while focusing on the mother and the infant, should also involve other members of the family for the mother to receive continued support so that she is able to engage with the intervention. An earlier study with British Pakistani women [10] reported that a major hindrance to social group participation was resistance from family members, particularly husbands.

A factor that helped with participation was the availability of free childcare to the participants at the intervention venue. In addition, some of the participants had older children; therefore, intervention sessions took place during term times. The Reay et al. [33] pilot study of group interpersonal psychotherapy for postnatal depression and research in the US [34] consider these to be key factors in improving engagement, particularly with hard-to-reach communities. Addressing transport arrangements was also reported to be an important factor in this study. The findings are also supported by Crockett et al.'s [35] study where lack of transport was found to be a barrier and women reported facing obstacles in getting transportation to the sessions. Chaudhry et al. [11] and later Gater et al. [17] also reported that provision of transport was an absolute necessity to ensure attendance to the intervention sessions by participants.

Furthermore, other difficulties raised by some participants were the inability to read and understand handouts written in English and the carrying out of between-session work due to personal and domestic commitments. There were, therefore, suggestions to add material in Urdu along with English, and some participants reported that completing the between-session work at home was not always a practical option for them due to time constraints. This needs to be considered in future research.

All the participants experienced an overall positive change in their attitudes, behaviours, and confidence. This positive change was attributed to a combination of facilitator input and coping strategies acquired over the 12 weekly sessions. The role of the facilitator was appreciated highly and the participants found the facilitator to be culturally aware and appropriately trained. The facilitator was open and communicative and this enhanced the overall process and led to increased positivity in the participants. Rahman [32] states that an understanding of the sociocultural context is essential for culturally-adapted interventions. In Rahman's [32] study the community health workers were from the same community as the women, and understood the sociocultural context of the women's problems which was found to improve engagement.

Because the PHP intervention was group-based, all the participants found factors such as sharing information, relating problems with each other, and gaining from the experiences of others helpful, and these contributed to their overall positive feelings. This is similar to the findings of Chaudhry et al. [14] and Gater et al. [10]. Some of the participants highlighted the need for some individual sessions along with the group sessions. They felt the need to talk about private matters to the facilitator on a one-to-one basis.

The impact of the PHP intervention was reflected in an overall positive change in participants' dealing with family members and children. Particularly participants reported feeling calmer and much more relaxed when dealing with their children.

Strengths and limitations of the study

A major strength of this study is the recruitment of participants from a hard-to-reach British South Asian community—Pakistani, Bangladeshi, and Indian women. An additional strength is the ability to engage depressed women during the postnatal period for up to 6 months, for follow-up assessments, and for interviews. Another strength of the study is the use of bilingual researchers which allowed participants to complete the interviews in their preferred language. This is one of very few studies looking at the overall process of development and implementation of culturally-specific psychological interventions for British South Asian women.

This study took place in the North West region of England; therefore, these results may not be generalizable to other regions in the UK. Most of the participants were of first-generation South Asian origin living in England. These participants were generally isolated and faced

additional social pressures. Another limitation of this study is the lack of availability of information from mothers who dropped out and did not attend any of the sessions. This information would have contributed to a deeper understanding of the acceptability of PHP intervention. Further limitation of this study is the conservative definition of completers which was 4 or more sessions out of 12 sessions. This is a conservative value because the mean number of sessions was 6. Another limitation of the study is the lack of inquiry into the impact of intimate partner or other forms of family violence on postnatal mental health problems among the participants. The intervention appears not to have focused on empowerment or other rights-based strategies. Since some of the quotes by the participants suggest coercion and control, further studies are required to gain a clearer understanding of these challenges.

Conclusions

The results suggest that this culturally-adapted psychological intervention is acceptable to British South Asian women. Furthermore, it appears from this qualitative study that culturally-sensitive psychological interventions can lead to better health outcomes and higher overall satisfaction levels. Interventions targeting postnatal depression in South Asian women should pay particular attention to ways of improving social support, independent coping strategies, involvement of the culturally-sensitive facilitator, language aspects, childcare and transport support, and group discussion techniques. Future research should consider including individual sessions in between group sessions to further improve engagement and perhaps health and social outcomes as well.

Competing interests

The authors declare that they have no competing interests in relation to this study.

Authors' contributions

YM conducted the interviews, carried out the analysis and drafted the manuscript. KL supervised the qualitative analysis and worked on editing the manuscript. FL assisted in conducting interviews and writing/editing the manuscript. NA helped develop the project and assisted in writing/editing the manuscript. WW helped develop the project and supervised. AR helped to develop the project and supervised data collection. RM revised the manuscript. NC was involved in the project development, supervision, and manuscript editing. NH led overall project development and supervision and contributed to the manuscript writing/editing. All authors read and approved the final version.

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Asian pearls

Treatment of maternal depression in urban slums of Karachi, Pakistan: A randomized controlled trial (RCT) of an integrated maternal psychological and early child development intervention

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ABSTRACT

Background: Maternal depression is a major public health problem. This may affect a mother's ability to provide adequate care for the child. The objective of this study was to evaluate the effectiveness of the Learning through Play Plus program (LTP Plus) – a parenting program integrated with Cognitive Behaviour Therapy (CBT).

Methods: A total of 247 women with symptoms of depression in Karachi, Pakistan were assigned randomly to either LTP Plus or routine care (Clinical Trials Identifier: NCT00835016). Symptoms of maternal depression were measured using the Edinburgh Postnatal Depression Scale (EPDS) at 3 and 6 months after baseline.

Results: At 3 months, there was a significant reduction in the EPDS scores in the intervention group compared to the routine group (adjusted mean difference [AMD] −3.65, 95% CI −6.14 to −1.15, $p < 0.004$). This effect was sustained at 6 months (AMD −2.62, 95% CI −4.43 to −0.81, $p < 0.005$). These women also reported less parental distress and disability. There was also a significant improvement in maternal knowledge about child development at 6 months.

Conclusion: There was a significant reduction in depression among women who received the group parenting program LTP Plus. This intervention has the potential to be scaled up and integrated with mother and child health programs.

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1. Introduction

Health of women during pregnancy, childbirth and the postpartum period is defined under solitary term of maternal health (World Health Organization, 2016). Depression during pregnancy or in the years following childbirth is a public health priority, both because of the high prevalence and the consequent suffering and disability of the mother (Rahman et al., 2004a; Masood et al., 2015) as well as the negative impact on the child's health and development (Tsivos et al., 2015; Patel, 2004; Rahman et al., 2004a, 2004b; Goodman and Gotlib, 1999). Infant cognitive and emotional development is adversely affected by maternal depression and can lead to poor child outcomes. (Tsivos et al., 2015; Murray and Cooper, 1997; Milgrom et al., 2004). Depression starting during the perinatal period is often persistent and may continue during the early years even up to 3 to 4 years after birth

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(McMahon et al., 2005; Kumar and Robson, 1984) which are considered to be critical period for child development (Howrwitz et al., 2009). Prevalence of maternal depression was reported as high as 15.6% during pregnancy and 19.8% after child birth (Fisher et al., 2012). A recent report from low and middle income countries suggests antepartum depression in one of four women and postpartum depression in one of five women (Gelaye et al., 2016). Frequently reported predictors of maternal common mental health issues in South Asian countries are poverty, lack of social support, adverse life events, disappointment with the sex of the baby and poor relationship with a mother-in-law or partner (Husain et al., 2011; Shidhaye and Giri, 2014).

In Pakistan, the rate of depression in women is amongst the highest in the world (Husain et al., 2000), and its impact, particularly on child growth and development, has been well-documented (Rahman et al., 2004b). Recent estimates from studies in developing countries showed prevalence of stunting and underweight as 32% and 20% respectively (Surkan et al., 2011). Pakistan like many other low income countries face malnutrition as one of the major child health issues (Rahman et al., 2004b). Literature show that compromised growth and development of child is associated with poor mental health of mother (Stewart, 2007). It is reported by various studies that children of depressed mothers are more at risk of poor development as compared to non-depressed mothers (Fisher et al., 2009; Tronick, 2009). Compromised child growth and development in low and middle income countries found significantly associated with maternal depression and the adverse effects may persist up to age of 8 years (Herba et al., 2016; Bennett et al., 2016). Interventions for maternal depression have been tested in low-income settings and cognitive behavioral approaches have been found to have the strongest effect in improving depressive symptoms in this group (Rahman et al., 2013a).

Given the impact of maternal depression on child outcomes, a strong case has been made for integrating interventions for maternal depression into general programmes for maternal and child health (Rahman et al., 2013b). Such approaches could potentially save costs (as the same health personnel would deliver the intervention) and lead to synergistic effects for both maternal and child outcomes. In Pakistan, studies have successfully tested the effectiveness of a Cognitive Behavioral Therapy (CBT)-based intervention for perinatal depression called 'The Thinking Healthy Programme (THP) in rural settings and mothers were recruited and assessed during their last trimester and the intervention was completed 12 weeks postnatally (Rahman, 2007; Rahman et al., 2013c). Evidence suggested that CBT is effective in minimizing postpartum depression when provided at individual level (Rahman, 2007); nevertheless it is likely to be cost effective when delivered in groups (Scope et al., 2013).

In the same settings in Pakistan, there is a report on the feasibility of a parent-based intervention for early child development—the Learning Through Play (LTP) programme that led to an improvement in knowledge, attitude and practices of depressed mothers about child development; however, no reduction was found in maternal distress (Rahman et al., 2009). The theoretical underpinnings of LTP are to be found in Piaget's theory of cognitive development (Piaget, 2013), and Bowlby's theory of attachment (Bowlby, 1999). The programme was originally developed in Toronto, Canada, using the stages and elements of development as defined by Evans (1982).

The aims of this study were three fold: first, to test the feasibility of combining the CBT-based intervention for symptoms of depression (THP) and the play/interaction-based early child development intervention (LTP) in a single integrated intervention as the previous trial showed that LTP alone did not show reduction in maternal distress and also the previous trials included mothers with infants whereas the focus of this trial was on mothers with young children up to age 30 months; second, to test the delivery of the intervention in a group rather than an individual format as in a study with British South Asians depressed women felt that meeting other people in similar situations and sharing experiences were major motivating factors for participation in the intervention sessions (Masood et al., 2015); and third, 'to test the effectiveness of this integrated intervention, in a low income setting

2. METHODS

2.1. Design

This was a rater-blind individual randomized controlled trial, with two parallel groups.

2.2. Study Area

The study was conducted at Bilal Colony and Bhatiabad. These are low-income urban areas of Karachi District in southern Pakistan. Karachi is the largest city in Pakistan with a population of approximately 25 million. The combined population of these two urban settlements is approximately 300,000. These areas have been constructed in an unplanned manner, typical of many such settlements in large South Asian cities. The study was conducted in both government and private primary care practices providing care to women and children. Ethical approval (PILL-LTP-0108-2008-9) was obtained from the Pakistan Institute of Living and Learning (PILL) Ethics Committee and the Trustees Committee of the Bilal Trust. No adverse events were reported during the implementation of the trial or longer-term follow-up.

2.3. Sample Size

The sample size was calculated based on Rojas et al. (2007). We expected 40% of the mothers receiving treatment as usual and 60% of the mothers in the LTP Plus group to recover from symptoms of depression within three months. A difference of 20% was regarded as worth detecting. Based on two-sided 5% alpha, 107 mothers needed to be recruited into each group to have 80% power of detecting the difference. We aimed to recruit 130 mothers into each group to allow for 20% attrition.

2.4. Participants

Screening and recruitment for the study started in 2009 and outcome assessments were completed in 2011. A total of 552 mothers with children aged up to thirty months attending the primary care clinics were approached by their health workers to take part in the study. Training was provided to all health workers on how to approach the mothers, introduce the research project, and get consent for initial screening. Out of these, 517 women completed the Edinburgh Postnatal Depression Scale (EPDS) out of which 412 mothers scored $\geq$12 (a cut off score of $\geq$12 was reported to be the most commonly used cut off to distinguish depressed cases from non-depressed group (Husain et al., 2012) and completed baseline assessments. After obtaining written informed consent, all eligible mothers were interviewed by a trained research assistant using the Revised Clinical Interview Schedule (CIS-R) (Lewis et al., 1992) to confirm the diagnosis of depression. This interview has been used in Pakistan earlier (Husain et al., 2014a).

A total of 338 women scored $\geq$14 on CISR. Out of these, 247 (73.08%) women met the study criteria: met diagnosis of depression, aged 18 to 35 years, and planning to reside in the study area for 6 months were included in the study. Women with

psychosis or a diagnosed physical condition requiring ongoing treatment were excluded. Depressed women recruited into the study were assigned randomly to intervention or routine care arms by an independent trial center in Karachi. Assessment was conducted by trained research assistants separately for each participant. Out of 247 women, 123 were randomized into intervention and 124 into routine care group. A total of 112 mothers from the intervention group and 110 mothers from routine care group completed the intervention and third month follow up assessments at the end of intervention. A total of 110 mothers from the intervention group and 96 mothers from the routine care group completed the six month follow up assessment after the baseline by blind raters; it was ensured throughout that the raters remain masked for assessment and participants were asked not to share the details of their intervention to the raters. Data on demographic and socio-economic status was also collected.

2.5. Study Intervention

The intervention, called LTP Plus, consisted of 10 group sessions delivered weekly in 60–90 minutes over 12 weeks. The intervention was delivered by graduate psychologists with limited clinical experience; however, they were supervised regularly by a senior clinical psychologist to ensure the fidelity of the intervention. Case conferences were held on a regular basis to discuss each group session. LTP Plus comprised of two components – Learning Through Play (LTP) and Thinking Healthy Program (THP). Each session was designed to include both components to form the LTP Plus intervention. The participants also continued to receive treatment as usual which consisted of routine follow-ups by lady health workers or traditional birth attendants. The LTP programme is intended to provide parents with developmentally appropriate messages to stimulate early child development in a culturally appropriate format. The central feature of the programme is a pictorial calendar devised for parents which depicts eight successive stages of child development from birth to 3 years along with illustrations of parent-child play and other activities that promote parental involvement, learning, and attachment. The first version of the LTP calendar – a pictorial booklet showing child development stages and play activities in each age and stage, was developed by the Toronto Public Health department for use by lay home visitors working with at-risk, multi-ethnic parents and children. It was later revised by The Hincks-Dellcrest Centre (2002). The 'Learning Through Play' (LTP) calendar is accompanied by a comprehensive training manual for workers (Ashem, 2002) which provides additional information on child development and techniques on how to conduct group or individual sessions for parents using the calendar as a focus. LTP is a low-cost intervention since homemade toys, books, and materials found commonly in the home are used to keep costs down to the minimum. The programme can be carried out by a variety of non-specialist staff (e.g. health workers, day care workers, lay home visitors) after appropriate training. The programme is flexible and can be delivered in a variety of formats with individual parents or groups of parents (e.g. a one-week workshop integrated with routine antenatal and postnatal visits, or spread over the first 3 years of the child's life with parent groups conducted at regular intervals). The LTP calendar is a relatively inexpensive and simple tool that relies minimally on the literacy of the parents. These attributes make it suitable for use in developing countries. Anecdotal evidence of the calendar's usefulness has come from India, China, Philippines, the Middle East, Peru, El Salvador, the Caribbean, and Canada. For the current study in Pakistan, we used the Urdu version of the calendar and the translated manual. Both the THP and LTP were field-tested and were used in our previous studies (Rahman, 2007; Rahman et al., 2009).

The THP manual includes step-by-step instructions for each session organized into five modules. Each module focuses on the following three areas: the mother's personal health, the mother-infant relationship, and the psychosocial support of significant others. The THP adopts a "here and now" problem-solving approach. It uses CBT techniques of active listening, changing negative thinking, collaboration with the family, guided discovery (i.e. style of questioning to both gently probe for the family's health beliefs and to stimulate alternative ideas), and homework (i.e. trying things out between sessions, putting what has been learned into practice) while educating participants about symptoms of depression, correlates and management, offering social support, and giving practical advice on using healthcare.

The LTP Plus supervisors carried out direct observation of the delivery of 2 sessions for each group. This observation aimed to assess the extent to which the LTP Plus THP contents were delivered as it was intended, by the group facilitator. Other than regular peer group supervision which also involved role plays the facilitators were provided with constructive individual feedback by the supervisor following observation of the sessions.

2.6. Treatment as Usual

The control group received treatment as usual which consisted of routine follow-ups by lady health workers or traditional birth attendants. Each Lady Health Worker (LHW) serves a population of 1,000 people in the community and also extends her services in the catchment population through monthly home visits. Their work includes covering all aspects of maternal, new born and child care. Province of Sindh has poor indicators in terms of maternal and child health care during and after pregnancy. The LHWs also provide family planning support and are also trained and taught about community organization, interpersonal communication skills, nutrition and child health i.e. Acute Respiratory Illness. The program of immunization is also carried out by LHWs. Moreover, hygiene domain is also covered by LHWs the focus of which is on clean drinking water and sanitation.

2.7. Primary Outcome Measure

Maternal depression was assessed using the Edinburgh Postnatal Depression Scale (EPDS) (Cox and Holden, 2003). This is a 10-item, self-report questionnaire and each item has four possible responses scored from 0 to 3. For example "I have felt happy", where 0 = *Yes, all the time* 1 = *Yes, most of the time*, 2 = *No, not very often* and 3 = *No, not at all.* Cutoff score $\geq$ 12 was suggestive of depression and depression was severe with high EPDS score (Husain et al., 2011). It is the most widely used tool developed specifically for screen r postpartum depression (Scope et al., 2013) and has shown good psychometric properties in Pakistan (Husain et al., 2012, 2014a; Rahman et al., 2005).

2.8. Secondary Outcome Measures

The Hamilton Depression Rating Scale (HAM-D) (Hamilton, 1967) was administered to assess the severity of depression. It is a clinician-rated instrument and in this study it was administered and rated by masters level research assistants. HAM-D has been used earlier with Pakistanis in the UK (Gater et al., 2010) and in an earlier study in Pakistan (Husain et al., 2011).

The Parenting Stress Index (PSI) Urdu version was used to identify stress in the parent-child relationship. PSI is designed for the early identification of parents who are at risk for dysfunctional

parenting, children with behavioral and emotional problems, and parenting and family characteristics that fail to promote normal development and functioning in children (Abidin, 1982). The higher the score the greater the parenting stress.

The Urdu version of the Rosenberg Self-Esteem Scale (Rosenberg SES) (Rosenberg, 1965) was used to measure self-esteem and personal worthlessness (Husain et al., 2014b). A higher score reflects a higher level of self-esteem.

The Multidimensional Scale of Perceived Social Support (MSPSS) (Zimet et al., 1988) was used to measure perceived social support. The MSPSS has been translated into Urdu and this has been used in earlier studies in Pakistan (Husain et al., 2006). The lower the score the lower is the perceived social support.

The Brief Disability Questionnaire (BDQ) (Von Korff et al., 1996) was used to assess disability. This questionnaire assesses disability in everyday activities and is comprised of 8 items rated from 0 (not at all impaired) to 2 (moderate or definitely impaired). Maximum possible score is 16 while disability will be higher the higher the total score. In this study the Urdu language version was administered which has been already used in Pakistan (Husain et al., 2011).

Mothers' knowledge and attitudes about the zero-to-36 month's stage of development was assessed at baseline and at 3 and 6 months using a specially developed Infant Development Questionnaire (IDQ). Higher score suggest greater knowledge of mothers regarding child development (Caldwell, 1967).

The children's weight and length (or height) was measured by standard anthropometry procedures used in an earlier study in Pakistan (Rahman et al., 2004b).

All the instruments have been used in Pakistan and are available in the local Urdu language.

2.9. Statistical Analysis

Intention to treat analysis was conducted. Preliminary analysis examined missing data patterns and the relationship between baseline characteristics and missing outcome data. Any characteristics found to be predictors of missing baseline scores data were

Table 1
Demographic Information.

		Control (n = 124)		Intervention (n = 123)	
		n	%	n	%
Mother's information					
Marital status	Married	124	100	123	100
Status of house	Owned	52	41.94	56	45.53
Access to clean drinking water?	No	81	65.32	87	70.73
	Yes	43	34.68	36	29.27
Mode of household waste disposal	In box with/without cover	68	54.84	71	57.72
	Outside the house	56	45.16	52	42.28
Work for income outside the house?	No	97	78.23	92	74.80
	Yes	27	21.77	31	25.20
Education	No education	99	79.84	81	65.85
Loss of a child?					
	Yes	34	27.42	44	35.77
Place of delivery	Maternity home/city/Town Govt. Hosp	56	45.16	53	43.09
Delivery conducted by	Local dai	65	52.42	68	55.28
Currently breastfeeding?	Yes	103	83.06	101	82.11
		Mean	**Std. Dev**	**Mean**	**Std. Dev**
Mother's age		27.26	5.50	28.20	5.47
Number of family members		8.94	4.60	7.86	3.96
Total monthly income (in rupees)		6266.13	2990.12	5910.57	2867.31
Total number of children		3.98	2.23	4.33	2.32
Fatherss information					
Education	No education	70	56.45	69	56.10
Income	Unemployed	19	15.32	15	12.20
Socioeconomic Status					
Have any debt?	Yes	75	60.48	77	62.60
Slept hungry in the last month?	Yes	52	41.94	57	46.34
Child's information					
Sex	Male	64	51.61	62	50.41
Vaccinated?	Yes	52	41.94	58	47.15
		Mean	**Std. Dev**	**Mean**	**Std. Dev**
Age (months)		15.34	8.41	15.62	8.36
Weight (kg)		9.82	3.48	10.97	3.79
Height (cm)		71.67	9.77	73.07	8.91
Days of diarrhoea		3.14	4.81	3.51	5.83
Days of chest infection		3.57	5.48	4.58	7.13

included in the final model to satisfy the assumption of maximum likelihood estimation that the data were missing at random. To allow for the clustering effect of the treatment groups in the intervention arm, two-level linear mixed models were used for primary and secondary analysis, with a random effect to measure between-group variation in the intervention arm. Treatment effect was estimated after adjusting for baseline outcome score, mother's age, mother's education, baby's gender, socioeconomic status, and baby's standardized weight. Heteroscedasticity was allowed for to prevent bias in the estimate of the variance components (Roberts and Roberts, 2005). Analyses were conducted in Stata 11 (StataCorp, 2009).

RESULTS

Total 247 mothers participated in this study of them 124 (50.2%) were in treatment as usual (TAU) group while 123 (49.8%) were in LTP Plus group. Table 1 presents the demographic data for the routine and intervention groups. The groups were comparable across demographic characteristics. There were 13% missing outcome data at 3 months and 17% at 6 months. Logistic regression was used to find predictors of the missing data. The baby's age, weight, standardized weight, and height significantly predicted missing outcomes at 3 months but only weight and standardized weight were significant at 6 months (Fig. 1).

A total of 11 mothers (8.9%) did not attend any LTP Plus group sessions; 18 (14.6%) attended 1-3 sessions; 30 (24.4%) attended 4-7 sessions; and 64 (52%) attended 8-10 sessions. The mean number of sessions attended by the mothers was 6.4 (SD 3.4). Maternal depression is presented in Table 2 as mean EPDS scores for the LTP Plus and TAU groups at baseline and follow-up alongside the adjusted mean difference. At both 3 and 6 months, the LTP Plus group had lower mean depression scores than the routine group, significant after controlling for the mother's age, mother's education, baby's sex, socioeconomic status, and standardized weight. The intra cluster correlation coefficient (ICC) was large, with 44% of the unexplained variation in outcome between intervention groups. This may have been due to the relatively small number of intervention groups.

Growth velocity was measured as the change in the baby's unstandardized height and weight from baseline to 6-month follow-up (Table 3). Table 4 shows that both height and weight were lower in the control group at each measurement occasion. However, the growth velocity did not significantly differ between groups after controlling for the set covariates.

Secondary outcomes adjusted for baseline outcome score, mother's age, mother's education, sex of baby, socioeconomic status and standardized weight, with random effects for intervention and control groups are presented in Table 5. It shows that mothers in the LTP Plus group also had lower levels of depression at both time points when measured using the HAM-D scale.

The LTP Plus group displayed significantly lower scores of parental stress and disability at both time points and had significantly higher self-esteem at 3 months. No significant difference was found for perceived social support between control and intervention group. IDQ scores were significantly higher for mothers in the LTP Plus group at 6 months. (Table 5)

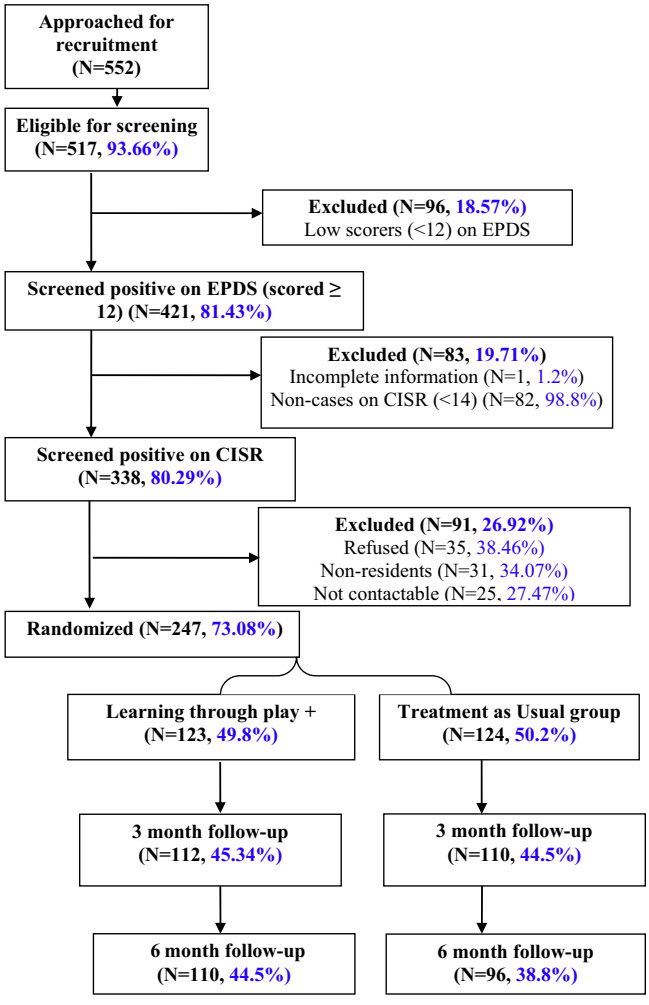

Fig. 1. Flow of participants through the Trial.

3. DISCUSSION

This randomized trial from two deprived urban slums in a low-income country shows that an integrated intervention combining cognitive behavioral techniques with parent-mediated, structured child play and interaction had a positive impact on maternal mood and led to a reduction in maternal depression. The intervention reduced maternal disability and parenting stress markedly, and led to improved maternal self-esteem. The intervention also improved maternal knowledge and practices with regard to early child development. There was significant reduction in EPDS mean score among mothers in LTP Plus group both at 3 and 6 months. Similarly significant difference was found among mother in LTP Plus group for severity in depression measured by a clinician rated scale, parental distress and disability both at 3 and 6 months while for self-esteem at 3 months and knowledge about infant development at 6 months. The study was successfully delivered in group settings in a routine primary care environment, demonstrating the potential for scaling up the programme and integrating it with maternal and child health programmes.

Compared with other trials of integrated interventions in low and middle income countries, we were successful in showing a strong positive impact on maternal depression. A South African study of the adaptation of the Health Visitor Intervention Programme incorporating principles of WHO's Improving the Psychosocial Development of Children programme (World Health Organization, 1999; Cooper et al., 1999) reported improvement in mother-infant interaction and attachment, but improvements in maternal mood were not significant. A recent systematic review also reported effectiveness of CBT in reducing postnatal depression (Scope et al., 2013). Group CBT when compared with usual care in two RCTs (Rojas et al., 2007; Honey, 2002) showed significant reduction in depressive symptoms using EPDS in intervention group. These findings are consistent with the outcome of our study. Conversely group CBT was also compared with waiting list in two

Table 2
Primary outcome adjusted for baseline Edinburgh Postnatal Depression Scale (EPDS), mother's age, mother's education, sex of baby, socioeconomic status and standardized weight, with random effects for intervention groups.

Intervention				Control			Adjusted mean difference (Intervention – Control)	(95% CI)	P value	ICC
EPDS	Mean	SD	N	Mean	SD	N				
Baseline	15.89	2.70	123	15.85	3.08	124	n/a	n/a	n/a	n/a
3 Months	10.29	5.29	112	13.86	4.50	104	−3.65	(−6.14, −1.15)	0.004	−3.65
6 Months	9.08	4.64	110	12.14	3.46	95	−2.62	(−4.43, −0.81)	0.005	−2.62

Table 3
Unstandardized weight and height summary data of child.

	Weight (kg)						Height (cm)					
	Intervention			Control			Intervention			Control		
	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD	N
Baseline	10.97	3.79	123	9.82	3.48	124	73.07	8.91	123	71.67	9.77	124
3 Months	12.75	3.43	112	11.50	3.02	110	76.56	8.63	112	74.70	8.98	110
6 Months	14.36	3.21	110	12.69	3.02	95	79.57	8.16	110	77.13	8.64	95

Table 4
Growth velocity adjusted for baseline EPDS, mother's age, mother's education, sex of baby, socioeconomic status and standardized weight, with random effects for intervention groups.

	Intervention			Control			Adjusted* mean difference (Intervention -Control)	95% Confidence Interval	P value	ICC
	Mean change	SD	N	Mean change	SD	N				
Weight	0.48	0.21	110	0.49	0.23	95	0.04	(−0.02, 0.10)	0.177	0.000
Height	0.92	0.50	110	0.92	0.50	95	0.04	(−0.11, 0.18)	0.613	0.003

nonrandomized studies and both studies reported greater improvement of EPDS in intervention group (Highet and Drummond., 2004; Meager and Milgrom., 1996). In rural Pakistan, the LTP programme without the cognitive behavioral strategies for mothers resulted in significant improvements in maternal knowledge and practices for infant development but did not achieve improvements in maternal mood (Rahman et al., 2009).

There is however, evidence of the effectiveness of parenting programmes in improving maternal mood as well as child outcomes. For example, a study of an intervention conducted in Jamaica consisting of extensive social support (weekly half hour home visits by a health worker for up to 2 years) improved mother's knowledge, child rearing practices and self-esteem (Baker-Henningham et al., 2005). It also aimed to encourage age-appropriate play activities and responsive feeding through empathic listening and praise (Baker-Henningham et al., 2005). However, the sustainability and cost of such an intensive programme inhibits its scalability. In India, a group-based participatory intervention was conducted with a focus on maternal and neonatal health, clean births, and care seeking (Tripathy et al., 2010). Maternal depression, although not a direct focus of the intervention, showed significant improvement, possibly as a result of social support available within the group and acquisition of problem-solving skills. Both programmes were universal, i.e. were targeted at all women instead of depressed ones only.

Our intervention targeted depressed women and we believe that combining the psychosocial techniques with the play strategies facilitated delivery and led to a synergistic effect. For example, the positive maternal mood, self-esteem, and motivation necessary for optimal interaction with infants and toddlers were promoted through the various cognitive behavioral and supportive strategies of the THP. The structured infant and toddler play and interaction activities of the LTP programme provided a framework to apply techniques of behavioral activation, where tasks were broken down into smaller components and depressed mothers were supported in achieving them through encouragement and praise, thus leading to a reduction in depression and disability. Similarly, the structured child play and interactional activities of the LTP, when sufficiently mastered, had a positive impact on maternal self-esteem and mood. Thus the two approaches combined to create a positive loop that benefitted both outcomes.

While the cognitive behavioral component may have been the more active ingredient to address depressive symptoms, we call the intervention Learning Through Play Plus because it was less stigmatizing to the mothers and more acceptable to the wider community. The early child development agenda provided a non-stigmatizing 'entry point' to engage the mothers and family members in the intervention. Earlier formative research (Rahman, 2007) has shown that many women do not view themselves as depressed, and have problems engaging in programmes that might label them as such. The early child development agenda helped engage not only the mother, but other significant family members including father and grandparents into the programme.

Furthermore, in low-income settings such integrated interventions should include other important key messages, such as those related to infant nutrition. An intervention incorporating the CBT techniques of the Thinking Healthy Programme into a combined child development and nutrition programme has been piloted successfully in rural Pakistan and is being evaluated for scaled-up implementation. This is important especially in the context of South Asia where up to 45% of all infants are malnourished (ACC/SCN, 2000). The LTP programme is currently being delivered in 33 countries across the world and can provide a platform for scaling up the LTP Plus intervention combined with a nutrition component both for the mother and the child.

Table 5
Secondary outcomes adjusted for baseline outcome score, mother's age, mother's education, sex of baby, socioeconomic status and standardized weight, with random effects for intervention groups.

Intervention				Control			Adjusted mean difference (Intervention − Control)	Effect size (adjusted mean difference/ pooled SD of baseline)	(95% CI)	P value	ICC
Depression Severity	Mean	SD	N	Mean	SD	N					
Baseline	19.15	3.69	123	18.98	3.37	124					
3 Months	9.60	6.05	112	15.95	5.87	110	−6.33	−1.79	(−8.60, −4.06)	<0.001	0.189
6 Months	10.57	5.97	110	14.49	4.43	96	−3.08	−0.87	(−5.60, −0.56)	0.016	0.327
Parental Distress											
Baseline	44.34	8.39	123	44.53	7.48	124					
3 Months	26.43	11.00	112	35.14	8.07	110	−8.75	−1.10	(−13.58, −3.92)	<0.001	0.373
6 Months	26.35	10.80	110	34.56	12.69	96	−6.76	−0.85	(−11.54, −1.98)	0.006	0.265
Self-esteem											
Baseline	15.63	4.10	123	15.01	3.98	124					
3 Months	19.63	2.30	112	17.42	3.13	110	1.99	0.49	(1.10, 2.89)	<0.001	0.128
6 Months	19.14	2.75	110	17.83	3.23	96	1.02	0.25	(−0.09, 2.13)	0.072	0.179
Disability											
Baseline	9.38	4.20	123	9.02	3.51	124					
3 Months	4.05	2.76	112	6.49	2.47	110	−2.53	0.49	(−3.29, −1.78)	<0.001	0.016
6 Months	4.75	2.82	110	6.09	2.59	96	−1.31	0.25	(−2.38, −0.23)	0.017	0.188
Social Support											
Baseline	40.46	13.89	123	41.53	13.45	124					
3 Months	41.11	16.33	112	36.98	14.67	110	3.32	0.24	(−1.48, 8.13)	0.175	0.056
6 Months	38.96	16.88	110	35.55	17.90	96	1.62	0.12	(−4.73, 7.97)	0.618	0.141
Mother's Knowledge and Attitudes about child Development											
Baseline	91.93	10.76	123	90.73	10.57	124		0.15			
3 Months	100.57	6.39	112	99.00	7.27	110	1.61	0.39	(−0.57, 3.80)	0.148	0.089
6 Months	102.29	5.23	110	97.96	9.57	96	4.20		(1.95, 6.46)	<0.001	0.000

4. LIMITATIONS

The intervention was designed for ease of implementation in a community setting; but we cannot be certain that our results are generalizable as this study was conducted only in urban slums that do not represent the larger rural population of Pakistan. However, such psychosocial interventions have already been tried with positive results in other developing countries such as Jamaica (ACC/SCN, 2000). A further limitation of the study is that child cognitive, social and emotional development was not measured. However, the reduction in parental stress and improvement in knowledge and practice of child development could be expected to positively influence these outcomes.

Author's Contribution

NH had the overall responsibility of the project. All authors contributed equally in writing the manuscript. TK was involved in delivering training and recruiting participants. CR and SH were responsible for the analysis and reporting of findings. FL, NC and IBC were involved in providing supervision in analysis and writing the manuscript. MH, FN and AR were involved in providing supervision to the project research staff.

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ORIGINAL ARTICLE

Randomized Controlled Trial

Group psychological intervention for maternal depression: A nested qualitative study from Karachi, Pakistan

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Abstract

AIM

To understand the experience of maternal depression, the factors implicated in accessing health, and the acceptability of the psychosocial intervention.

METHODS

The participants were recruited from the paediatrics outpatient department of Civil Hospital Karachi, Pakistan. The study started in December 2009 and completed in December 2010. Women with maternal depression, aged 18-44 years with children aged 0-30 mo who had received nutritional supplements, and participated in the intervention programme [called Learning through Play (LTP) plus] were included in the study. Qualitative interviews were conducted with 8 participants before the intervention and 7 participants after the intervention. A semi structured topic guide was used to conduct the interviews.

RESULTS

Framework analysis procedures were used to analyse the qualitative data. Four themes emerged: (1) the women's contextual environment: Interpersonal conflicts, lack of social support and financial issues being the major barriers in assessing healthcare; (2) women's isolation and powerlessness within the environment: Sense of loneliness was identified as a restricting factor to access healthcare; (3) the impact of the intervention (LTP-Plus): Women felt "listened to" and seemed empowered; and (4) empowered transformed women within the same contextual environment: The facilitator provided a "gardening role" in nurturing the women resulting in a positive transformation within the same environment. The women's homes seemed to be more happy homes and there was a positive change in their behaviour towards their children.

CONCLUSION

Findings informed the further development and testing of culturally-appropriate psychosocial intervention (LTP^{+}) for addressing maternal depression.

Key words: Low income Country; Thinking Healthy Program; Learning through play; Maternal depression; Framework analysis; Exploratory analysis

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Core tip: To our knowledge this is the first qualitative study from Pakistan exploring the experiences of depressed mothers participating in a group psychosocial intervention trial. This was part of a randomized control trial testing the acceptability and feasibility of a parenting intervention Learning through Play (LTP)-Plus among depressed women in a low-income setting. The LTP^{+} intervention focused on two key objectives. First was to stimulate early child development through a pictorial calendar among children from birth to 3 years. Second was to change negative thoughts patterns of mothers through culturally adapted cognitive behavioural therapy intervention. The intervention was acceptable and the qualitative data informed the further development of the intervention.

Husain N, Chaudhry N, Furber C, Fayyaz H, Kiran T, Lunat F, Rahman RU, Farhan S, Fatima B. Group psychological intervention for maternal depression: A nested qualitative study from Karachi, Pakistan. *World J Psychiatr* 2017; 7(2): 98-105 Available from: URL: http://www.wjgnet.com/2220-3206/full/v7/i2/98.htm DOI: http://dx.doi.org/10.5498/wjp.v7.i2.98

INTRODUCTION

Childbirth has been recognized as an important life event that alters responsibilities of a woman permanently[1]. The transition to motherhood is characterized by rituals, prohibitions, and guidelines that facilitate mothers' adaptation to their new roles[2]. However, lack of social support and stressful life events during this significant transition may lead to depression[3,4]. In the West, 10%-15% of women are affected by maternal depression[4] and its prevalence is much higher in developing countries such as India (28%)[5] and South Africa (34.7%)[6]. The prevalence rate is even higher among Pakistani women, *i.e.*, 36%[3]. Increased psychological distresses during the antenatal period[3,5], worry about debt[7] poverty, and disturbed marital relationships[5] have been identified as risk factors for maternal depression.

Furthermore, a phenomenological study in Hong Kong highlighted feelings of "being trapped" in women with postnatal depression and explained that lack of support in the form of uncaring husbands and controlling in-laws were emergent themes along with mothers' ambivalent feelings of love and hate towards their baby[8]. The mother is responsible for breastfeeding, maintaining hygiene for the child, and immunization. She is expected not only to recognize illness, but also to seek appropriate care and treatment for her child[9]. Symptoms of maternal depression such as tiredness, inability to concentrate, preoccupation with guilt, worthlessness, and hopelessness adversely affect a mother's ability to provide adequate care[10]. This may have a long-term impact on the child's physical as well as psychological and cognitive well-being[11]. Results of cohort studies from developing countries including South Africa, Pakistan and India report strong associations between maternal depression and stunted growth[5,12,13]. Similarly, the damaging effects of maternal depression on intellectual and psychological development are also well documented[14,15].

The effectiveness of different psychological interventions such as cognitive behavioural therapy (CBT), interpersonal psychotherapy, and problem-solving therapy is well

established in the treatment of depression in developed[16] as well as developing countries[17]. A multicomponent intervention that involved psychoeducational treatment adherence, support, and pharmacotherapy was found to be effective in reducing depression in women with postnatal depression in Santiago[18]. In Pakistan, intervention based on the principles of CBT was found to be effective in reducing depression and disability and in improving social functioning[19].

A qualitative systematic review by Dennis and Chung-Lee[20] highlighted inability to disclose feelings, the presence of myths and lack of knowledge as barriers to help-seeking behaviours in women suffering from depression. Furthermore, this review also reported a preference for "talking therapies" for the treatment of postnatal depression[20].

As far as we are aware, the present study is the first qualitative research in Pakistan which explores the experiences of women suffering from maternal depression in Pakistan and their related experiences of participation in a group psychosocial intervention trial. A mixed-method study was conducted that comprised a randomized controlled trial (RCT) to test a psychosocial intervention for reducing maternal depression and improve child outcomes. A qualitative method was also used to understand the experience of maternal depression, factors implicated in accessing help, and the acceptability of the group psychosocial intervention in the participants.

MATERIALS AND METHODS

A qualitative approach was adopted as the research design. This approach was chosen in order to understand the experience of maternal depression in the cultural context of these participants, and to explore the antecedents, manifestation, and consequences of depression. Another area that was targeted in this study was the experience of participation in a group psychosocial intervention by particularly focusing on the helpful parts of the intervention, and the difficulties faced by the participants. The participants were interviewed before and after taking part in the intervention. Data was analysed using framework analysis principles[21,22]. All the mothers aged 18-44 years with children between 0-30 mo, diagnosed with depression on Edinburgh Postnatal Depression Scale (EPDS score $\geqslant$ 14) and residents in the trial catchment site were included in the study. Mothers with a medical disorder that could prevent their participation in the trial and those with active suicidal ideation or any other severe physical/mental disorder were excluded.

Ethical approval for the study was sought from the Institutional Review Board of Dow University of Health Sciences, Karachi, Pakistan. A Participant Information Sheet was provided to all participants at the time of recruitment and queries were addressed. After providing a detailed description of the study, written informed consent was obtained from all participants. Participants were assured of confidentiality and permission was obtained to audio record interviews. Codes were assigned to each participant and all transcripts were anonymised during transcription to keep personal data confidential. Data was kept safe on encrypted and password protected computers and were transferred electronically using encrypted files. A Lone Working Policy was used by Pakistan-based researchers in order to ensure their safety in the field. Furthermore, a Distress Policy was in place to enable the researchers to have a framework for accessing further support for participants when it was clear that someone could be at risk. The participants were interviewed at Civil Hospital Karachi, because it was a convenient place for the participants.

This study was a part of an RCT in which the acceptability and feasibility of a group psychosocial intervention [Learning through Play (LTP) Plus] was tested to reduce maternal depression and improve child outcomes. The LTP program focuses on the strategies to stimulate early child development. A pictorial calendar is the main feature of this program that is designed for parents and includes eight successive stages of child development from birth to 3 years. The second component of the psychosocial intervention was cognitive behaviour therapy (CBT) that was aimed at changing negative thought patterns. This study comprised of 98 participants; half of whom were randomized into the intervention group (n = 49) and half into the control group (n = 49). Participants were included in an in-depth interview study through convenient sampling. Interviews were conducted with 7 participants from the routine treatment group and 8 participants from the LTP plus in addition to routine treatment. Initially, 25 participants were invited at random to participate in qualitative interviews; 10 refused to participate because they did not want their interviews to be recorded whereas 15 participants consented. In-depth, semi-structured interviews were conducted by trained researchers. All were trained psychologists and received additional training on qualitative research and data analysis. All interviews were audio recorded after obtaining participant consent. Two separate topic guides were prepared for pre-intervention interviews and post-intervention interviews. The purpose of the interviews with the routine treatment group was to explore experience of maternal depression, its causes and manifestation, and the state of available treatment options. However, interviews conducted with the LTP Plus group were focused on exploring the experience of participation in a group psychosocial intervention, and to identify facilitators and barriers to accessing the intervention. After each interview, field notes were made by the researcher to document the body language of the participant in response to questions along with any other relevant information.

All interviews were transcribed verbatim in Urdu and then translated into English for data analysis. The routine treatment group data and LTP plus group data were analysed separately and then integrated during the mapping and interpretation phases[23]. The five stages of

framework analysis were used to analyse data[21]. During the initial familiarization stage, three researchers (HF, TK, BF) read through the transcripts and field notes collected during the interviews several times to fully immerse themselves in the data. After all data were familiarized, and in order to identify the key themes, a draft theoretical framework was constructed in which major and minor themes were identified from all interviews. Indexing was then carried out in order to apply the draft theoretical framework systematically to the data. Here the data from transcripts were copied and pasted alongside the relevant themes that were listed in the draft theoretical framework. Data and themes were then compared again and the draft theoretical framework revised. During the charting process, data were summarized into table developed using MS Word software for each theme listed in the draft theoretical framework[24]. This process provided a clear and concise overview of the data. Finally, these tables were reviewed during the mapping and interpretation phase. This enabled all key ideas and the data to be compared and discussed by researchers and supervisors, and to identify the final theoretical framework that synthesized and interpreted the data as a whole. To maintain credibility and trustworthiness of the data and subsequent findings, the researchers in Karachi were supervised by experienced mental health and qualitative researchers (NC, FL, CF) based in the United Kingdom. Regular fortnightly Skype meetings were held to discuss progress with the study team during the data collection and analysis phases. Drafts of analyses were electronically mailed to researchers in the United Kingdom who were able to study these before the Skype meetings. The organization (structure and pace) of the supervision process enabled the Pakistan-based researchers to develop experience, skills and confidence in qualitative methods. Engagement in discussion and regular reviews by all researchers ensured fit of the data to the final analysis, and supported minimization of bias[24]. Team members met for the final review of the theoretical framework, and came up with similar ideas. Furthermore, translations from Urdu to English were back-translated to ensure accuracy. For respondent validation[25], 15 participants were approached for feed-back, out of those 9 agreed to give feedback on accuracy of the data. Researchers and group members agreed on the key themes and interpretations.

RESULTS

All participants were home maker women aged 36-40 years, married, with children aged of 0-36 mo. After completion of data analysis, the following 4 key themes were identified in the final theoretical framework.

Context-the women's environment

This theme identifies the psychosocial factors that co-existed with women suffering from maternal depression. Interpersonal conflict and lack of support from extended family members were highlighted in many interviews. For example, the data suggest that several women were experiencing financial hardship which was the main barrier to accessing healthcare facilities. In this setting, it is common for healthcare to be paid for by the service user as state-funded services are minimal. The following quotes illustrate these points.

My sister-in-law often has arguments with me. She does not take care of my children when they cry (Participant 1). Who will understand? My husband thinks that I am bad. My children also think that I am bad (Participant 3). Participants reported that they were suffering from severe financial hardship because of their partners' unemployment and were unable to access treatment for their ill children which they also had to pay for. My husband stays at home not doing anything. He has not been going to work for the last 2 years (Participant 6). Yes he earns but how much can an ill person earn? (Participant 4). My child falls ill very frequently (Participant 1). There is illness but the actual problem is poverty. We don't have money (Participant 2). Children are becoming timid and frightened; they cry because of the circumstances (Participant 5). Participants were unable to contribute financially to the household because of cultural attitudes against their going out to work[16]. It does not happen in our home (community) that women go for work and men do not go. I will go secretly after my husband will leave for work (Participant 8).

Participants also expressed dissatisfaction with the healthcare services available to them. The participant reported that most of the doctors did not provide adequate attention and appropriate treatment to the patients. She does not provide (proper) treatment; simply gives medicine and injection (Participant 1). Sometimes when a good doctor is available he attends us well, but most of the time they just ignore (Participant 2). He (doctor) does not check properly. Here doctors are just like this. No one checks, they just come and leave (Participant 3). You know well how doctors in the government setup are. They do not listen to us. There are so many patients and doctors do not bother with them (Participant 4). What kind of treatment? I had spiritual treatment but it did not have any benefit; reduced my anger just a little bit (Participant 6). Treatment can be provided by a doctor. He should give medicine and also listen to us (Participant 8).

Women isolated and powerless within the environment

The data suggest that prior to the intervention, women were thinking very little about themselves and felt very alone. They were unable to seek support outside the home and described a sense of "paralysis". Some women reported symptoms of physical illness. They were keeping themselves isolated and felt they had no support. There is no use to share this. Who will understand our problems? (Participant 3). I do work. What can I do? There is no one else who can do my work (Participant 4). Whom should I talk to, who would understand, who

would help? (Participant 7). Because of the lack of support and feelings of helplessness, the participants experienced sadness. Before (intervention) I felt sadness and a lot of anxiety and also felt myself alone (Participant 7). I remained sad and worried all the time before (intervention) and I could not find a solution for any of my problems (Participant 6). Because they were keeping themselves isolated and little support was available to them, the participants expressed this sadness in the form of anger. I get very angry (Participant 1). I cry, remain worried. What else can I do? (Participant 2). I get upset, not knowing what to do. I pray but also get angry (Participant 8). I feel like I want to take poison and kill myself and my children too (Participant 7). I started fighting with others without trying to understand what they were saying. If my husband said anything I would start fighting immediately. I used to say anything in state of anger (Participant 4). Furthermore, because of their emotional state, the participants lost interest in participating in routine activities of their daily life, such as looking after the house and their children. I just sit at home, cannot do anything. I just sit idle (Participant 6). I did not have interest in anything (Participant 1). I do not want to play with my children although I know it's important but still I am not interested in doing this (Participant 5). The disturbed emotional state often provoked them to beat their children which consequently made them feel more upset and guilty. When I was angry, I often used to beat my children (Participant 3). Earlier I used to think bad about myself (Participant 2).

The impact of the intervention

After completing the intervention, the participants were clearly demonstrating a more positive nurturing role. They appeared lesser isolated and were interacting more positively with others. They displayed a sense of empowerment following the intervention and demonstrated that the intervention enabled them to be more confident in their roles.

Now I have become more confident (Participant 2). They appeared now to have the strength and courage to attend to and interact with their children. They were more involved in the care of their children, for example, washing them adequately, teaching them etiquette, and playing with them. Some misconceptions seemed to be present in the community such as mothers believing that showing children their reflection in the mirror will make them ill-that if they showed a mirror to their child, he/she will get mad or get diarrhoea. After participating in the LTP Plus intervention, mothers learned to challenge this belief and appreciate the positive outcomes of using a mirror during child play. These quotes explain these behaviours. Now I feel good, take care of myself and the children as well. Now I do not get obsessed with worries like I was before (Participant 3). Through this program I got more information regarding children; like I did not show mirror to my child before but now I show them mirror (Participant 2).

Yes, we should play with children. They like their parents behaving like a child in front of them. This makes children happy and me as well (Participant 1). What I learned about children is that we should teach them etiquette when they are young. When elders use abusive language children understand that and also repeat that in their mind (Participant 4). I liked the part related to children because I feel happy when my child is happy (Participant 6). I liked the part related to children because before (intervention) I did not treat my children well, dealt with them harshly, but after attending the intervention I learned how to spend time with children and how to understand them (Participant 7). They also developed skills in observing and evaluating others and themselves, and also thinking about others. They were now able to solve problems when faced with difficulties and appeared to be more rational in their thinking about daily life activities. They were now thinking more outwardly, rather than inwardly. My mind has been changed since I participated in the program; now I try to solve my problems myself (Participant 5). We should keep on looking for other solutions; at least one (solution) will definitely work. This encouraged me a lot (Participant 7). Yes, all negative thoughts are gone away (Participant 1).

Empowered, transformed women within the same environment

The facilitator was seen as the catalyst for the change in the women. This was a novel experience for the participants as; previously, many of them did not have anyone to share their personal feelings with. They were happy that the facilitator was a female, and they felt that she provided more support and understood them and their feelings well. The facilitator's role can therefore be likened to a "gardeners role", nurturing the women to enable them to foster and transform within their environment.

She focused on each and every point, talked slowly and thoughtfully (Participant 1). Yes, doctor (interventionist) elaborated things very well and I did not have any problem in understanding. She tried to teach us things very calmly and in a good manner (Participant 2). I liked her style of teaching the most. She used to tell everything very slowly and calmly (Participant 3). No, there was no difficulty (in understanding session) (Participant 5). Sister (interventionist) used to teach us slowly and with love. She repeated the things we did not understand (Participant 6). She tried to teach slowly and with love (Participant 7).

To summarize these findings, the environment that these women lived in before taking part in the intervention can be likened to an "infertile garden landscape" where flora is not able to grow and thrive. Furthermore, the "gardeners", or healthcare providers in this case, are not able to provide any support freely, or to nurture their inhabitants in the surrounding area. When medical help was sought by these women, the assistance was not appropriate and did not meet their needs. This

can be likened to the "gardeners" being somewhat irresponsible and reckless as they did not pay adequate attention to these women and their health concerns. Before the intervention these women can be described metaphorically as "closed, dormant rosebuds in the garden", who were experiencing feelings of loneliness and sadness. However, the data indicate that after participating in the LTP Plus intervention the women can be compared to a "vase of blossoming roses" who are now blooming and prominently emitting confidence, knowledge, and self-assurance. Furthermore, the facilitator or deliverer of the intervention was observed as a nurturer/cultivator who attended to their needs with care, love, and attention. Hence, this role can be likened to a "nurturing gardener" who tends carefully to the plants and foliage in their surrounding landscape. Following the LTP Plus intervention, most of the women's homes (the landscape) were transformed into happy homes where the women were interacting more positively with their children.

DISCUSSION

The qualitative approach and framework analysis method of data analysis has clearly identified themes that provide a detailed explanation for the participants' feelings of psychological distress before the intervention. The method has also enabled the changes to be identified after participating in the study. The participants' environment was characterized by deprivation of financial and economic support. Worry about the employment of the partner and interpersonal conflict have been reported by the participants as a contributing factor for maternal depression. Social adversity has been reported to be associated strongly with maternal depression in differing contexts in previous studies[7]. A study in India reported economic deprivation as a risk factor for maternal depression[26]. Studies reported that unhealthy social environment and experiencing lack of social support (including difficulties in relation to people: Friends, partners, trusted people, and relatives) have strong associations with maternal depression[27]. Results of a qualitative study conducted in four cities of south-western Finland reported that lack of a caring attitude from the husband and controlling and powerful in-laws were associated factors for symptoms of hopelessness. Helplessness and loss of control were noted among Chinese women in Hong Kong suffering from maternal depression[8]. A previous study conducted in Pakistan reported that social support and stress contributed greatly to postnatal depression compared to poverty and financial issues[3]. Women in the present study reported that they were unable to contribute financially as many women in their culture are not allowed to go out for work. South Asian women are dependent on men socially and economically[28] and are restricted not only in their mobility but also in decision-making and use of resources[29]. A qualitative study of postnatal depression across countries and cultures reported that a universally accepted remedy to deal with postnatal depression was to increase social support from the family and emotional support from the husband[1].

A second theme of this study was related to women being isolated and powerless in their environment. This theme was basically about the expression of depression among women. They expressed their depression in the form of sadness, hopelessness, anger, physical symptoms, and lack of interest in the environment. They also reported that they directed their anger to their children. Depression has been reported to be a debilitating disorder with symptoms of low mood, low self-esteem, tiredness, and lack of interest[30]. Research also supports that depressed mothers are tired and unable to concentrate and they experience feelings of guilt, worthlessness, and hopelessness[10]. As these women were often unable to provide proper attention to their children because of their depression, they directed anger towards their children and ultimately felt guilty. Moreover, medically unexplained symptoms (MUS) have been recognized as the most prevalent type of symptoms in primary care[31]. MUS can be the representation of recognized psychiatric disorders such as depression or anxiety and can be manifested in various forms including chronic fatigue syndrome, irritable bowel syndrome, fibromyalgia, or simply as symptoms that exist in the absence of a defined organic diagnosis. Evidence suggests that MUS being more common in Asian and African cultures[32]. Findings from a previous study conducted in Pakistan reported that although the proportion of MUS (35%) was similar to what is reported in the West, unlike western studies MUS were twice as common in women than in men and these symptoms led to inability to perform work[32]. Results of a previous qualitative study reported that women with postnatal depression felt helpless and they somatised their depression[33].

The third theme was related to women reporting the positive effects of the LTP Plus intervention. They felt that they became more empowered after the intervention and their knowledge about child rearing improved. They reported better ways of dealing with their children and improvement in problem-solving and their feelings after attending the intervention. In an earlier qualitative study assessing the role of psychosocial intervention in postnatal depression, women described the intervention as a positive experience and found it acceptable and successful. They also reported a positive impact of the CBT approach in influencing thought patterns that led to positive and negative feelings[34]. The LTP intervention was reported to be effective in increasing mother's knowledge of child development[35]. Results of a previous study testing the Thinking Healthy Program (THP) based on the principles of CBT reported that rates of depression were reduced among women receiving this intervention compared to those receiving enhanced routine care. Women in the intervention group experienced more symptomatic relief, and better social adjustment than the comparison group[19]. This was the first time a combination of both interventions was tested, *i.e.*, LTP and CBT (THP).

It led to improvement in mother-child interaction and reduction in depression, as reported by the participants.

The final theme was about the satisfaction of the participants with the LTP Plus group facilitator. They reported that the facilitator helped them to feel empowered even within their difficult environment. Participants appreciated the communication style and patience of the facilitator. The relationship between the role of communication and the effectiveness of intervention for reducing depression in primary care has already been explored[36]. It is recommended that all the healthcare providers dealing with maternal depression should adopt a non-judgmental and accepting approach[34].

Strengths and limitations of the study

There was a high participation rate, with 15 out of 25 (60%) eligible women agreeing to participate in the study. The framework analysis process and the integral phases work well when supervising at a distance as each stage provides a logical opportunity for discussion and review with team members. This fostered a thorough and comprehensive consideration of all aspects of the research process. The multidisciplinary backgrounds of the research team (mental health, midwife, clinical psychologist, research) facilitated emergence of key ideas in the data. Because of the small sample size, the findings cannot be generalized. Moreover, female facilitators were more acceptable to the participants. The findings from women with mild to moderate depression may not be extrapolated to women with severe depression. Some interviews were not as detailed as others because women in this context are not used to accessing services and discussing their problems. Seeing health professionals is not a common practice and thus they are not familiar with talking about their feelings. Thus, the interview experience is slightly novel to them.

Reducing child mortality and morbidity has received attention as a Millennium Development Goal worldwide. However, in low and middle-income countries the process of development of cost-effective psychosocial interventions to achieve such a goal is slow. The present study gives direction in developing and testing culturally-appropriate psychosocial interventions for reducing maternal depression in order to work towards the sustainable development goal.

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COMMENTS

Background

Prevalence is much higher in developing countries such as India (28%) and South Africa (34.7%). The prevalence rate is even higher among Pakistani women, *i.e.*, 36%. Results of cohort studies from developing countries including South Africa, Pakistan and India report strong associations between maternal depression and stunted growth. In Pakistan, intervention based on the principles of cognitive behaviour therapy (CBT) was found to be effective in reducing depression and disability and in improving social functioning. However studies highlighted inability to disclose feelings, the presence of myths and lack of knowledge as barriers to help-seeking behaviours in women suffering from depression.

Research frontiers

Major changes occur during the postnatal period which determines the well-being of mothers and newborns, but unfortunately this is the most neglected period in terms of provision of quality services. Maternal depression accounts for the largest proportion of burden associated with mental or neurological disorders and have strong association with increased child mortality. There is now evidence from some low income countries that effectively delivered psychosocial interventions that are cost effective for improving maternal and child health.

Innovations and breakthroughs

This study was a part of a randomized controlled trial in which the acceptability and feasibility of a group psychosocial intervention [Learning through Play (LTP) Plus] was tested to reduce maternal depression and improve child outcomes. The LTP program focuses on the strategies to stimulate early child development. A pictorial calendar is the main feature of this program that is designed for parents and includes eight successive stages of child development from birth to 3 years. The second component of the psychosocial intervention was CBT that was aimed at changing negative thought patterns. CBT based intervention called Thinking Healthy Program (THP) was successfully tested to reduce postnatal depression in rural area of Pakistan. A parent based intervention LTP was also tested in the same setting that led to the improvement in knowledge, attitude and practices of depressed mothers about child development, however no reduction was found in maternal distress. Therefore the aim of the present study was to explore the acceptability and feasibility of combination of two interventions, *i.e.*, LTP plus THP (LTP Plus) to reduce maternal depression and improve child health.

Applications

The present study is the first qualitative study conducted in Pakistan to explore the role of culturally adapted intervention to improve maternal mental health and child health outcomes for undernourished children brought to paediatric units. There is a need to conduct such studies so that this low cost culturally appropriate intervention can be integrated into the existing health care system to improve maternal and child health in Pakistan and other low income countries.

Terminology

Framework analysis: Framework analysis is a method of qualitative analysis and it is case and theme based approach, reduces data through summarization, retains links to original data, and allows comprehensive and transparent data analysis; THP: THP is based on principles of CBT like listening, identifying and changing negative thoughts and emotions, problem solving skills, *etc.*; Cultural adaptation: Cultural adaptations are changes to intervention content or process that addition, deletion, or alteration to the components, changes in intensity of the intervention and cultural or other contextual modifications.

Peer-review

It is well written.

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Multicentre randomised controlled trial of a group psychological intervention for postnatal depression in British mothers of South Asian origin (ROSHNI-2): study protocol

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Background

In the UK, postnatal depression is more common in British South Asian women than White Caucasion women. Cognitive–behavioural therapy (CBT) is recommended as a first-line treatment, but there is little evidence for the adaptation of CBT for postnatal depression to ensure its applicability to different ethnic groups.

Aims

To evaluate the clinical and cost-effectiveness of a CBT-based positive health programme group intervention in British South Asian women with postnatal depression.

Method

We have designed a multicentre, two-arm, partially nested, randomised controlled trial with 4- and 12-month follow-up, comparing a 12-session group CBT-based intervention (positive health programme) plus treatment as usual with treatment as usual alone, for British South Asian women with postnatal depression. Participants will be recruited from primary care and appropriate community venues in areas of high South Asian density across the UK. It has been estimated that randomising 720 participants (360 into each group) will be sufficient to detect a clinically important difference between a 55% recovery rate in the intervention group and a 40% recovery rate in the treatment-as-usual group. An economic analysis will estimate the cost-effectiveness of the positive health programme. A qualitative process evaluation will explore barriers and enablers to study participation and examine the acceptability and impact of the programme from the perspective of British South Asian women and other key stakeholders.

Keywords

Perinatal psychiatry; depressive disorders; cognitive–behavioural therapies; psychosocial interventions; randomised controlled trial.

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Postnatal depression is a major public health concern because of its negative effect on mothers, including relationship problems[1,2] and an increased risk of future depression. In the UK, postnatal depression is more common in British South Asian women than White women.[1,3] Postnatal depression also negatively influences the psychological and cognitive development of children.[2] Postnatal depression is treatable,[4,5] but women can be reluctant to disclose symptoms and seek help because of stigma.[6,7] Antidepressants can be an effective treatment, but new mothers can be reluctant to use them because of concerns about side-effects.[4,5] Cognitive–behavioural therapy (CBT) has been shown to be effective for postnatal depression[4,5] and is endorsed as a first-line treatment.[8] However, there is little empirical evidence for the adaptation of evidence-based treatments, including CBT, to ensure their applicability to different ethnic groups.[9,10] There is value in cultural adaptation and a need to test the effectiveness of adapted interventions for ethnic minority groups.[11]

The need for culturally adapted CBT

The positive health programme (PHP) is a culturally adapted group CBT intervention for postnatal depression[10] that has been developed by our research group in an exploratory randomised controlled trial (RCT) (Exploratory RCT of a Group Psychological Intervention for Postnatal Depression in British Mothers of South Asian Origin; ROSHNI-D),[12] and we were able to show the feasibility and acceptability of the present trial. A sufficiently powered trial is needed to confirm the preliminary findings of ROSHNI-D, to test both short- and longer-term outcomes, and to answer additional research questions, including the cost-effectiveness of PHP. The focus of the proposed study is a group CBT intervention for British South Asian women with postnatal depression and psychosocial difficulties. These women often live in low-income areas and, because of their psychosocial problems, language and cultural barriers, they are deemed 'hard to reach' and hard to engage. South Asian people comprise the largest ethnic minority group in the UK, representing around 7.5% (4 214 000) of the population,[13] and have one of the highest birth rates in the UK. There are now policies that endorse the need for a range of effective therapies, including psychotherapeutic treatments, that are culturally appropriate and effective.[14]

Aims and hypothesis

The present trial, ROSHNI-2, aims to evaluate the clinical and cost-effectiveness of the PHP intervention added to treatment as usual (TAU), compared with TAU only, in British South Asian women with postnatal depression. *Roshni* means light in Urdu/Hindi. The primary hypothesis is that participants who receive PHP added to

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TAU will have reduced levels of postnatal depression, as measured by the Hamilton Rating Scale for Depression (HRSD),[15] compared with participants receiving TAU only, 4 months after randomisation (end of intervention). HRSD scores at 4-month follow-up will be the primary outcome measure. Costs associated with health and social care resource use will be collected, and each participant in the trial will be asked to complete the EuroQol EQ-5D instrument at each follow-up, and these responses will be converted to quality-adjusted life years (QALYs). Follow-up at 12 months will provide evidence of long-term outcomes. A qualitative process evaluation will explore barriers and enablers to study participation, and examine the acceptability of PHP from the perspective of British South Asian women, the impact of PHP on healthcare practice from the perspectives of general practitioners (GPs), and the experiences of being trained in and delivering PHP from the perspectives of group facilitators.

Method

Design

This is a multicentre, two-arm, rater-blinded, partially nested RCT with post-intervention (4 months) and 12-month follow-up, comparing PHP and TAU with TAU only, for British South Asian women with postnatal depression. There is a likelihood that because of the reciprocity between participants during the group PHP intervention, they will respond in a similar manner and their outcomes will be more alike than for women in different groups. This leads to a clustering effect in the intervention condition similar to that found in cluster randomised trials. The trial design adopts a partially nested design with participants in the intervention arm nested in therapy groups compared with the control arm participants, who are not nested. Economic and process evaluations are also embedded in the trial. The trial is registered with Clinicaltrials.gov under registration number ISRCTN10697380.

Internal pilot phase

An internal pilot phase is integrated into the trial, with clear STOP/GO criteria to prove viability to proceed to a full trial across all study sites. Success criteria during the internal pilot study phase (months 5–14) will be gauged by recruitment of at least 200 participants. In case this is not possible and we face difficulties in achieving the target, we will look into the possible shortcomings and have a 'rescue plan' ready for deliberation by the Trial Steering Committee and National Institute for Health Research approval.

STOP/GO criteria are as follows: GO if ≥180 participants are recruited into the study (target minus 10%), implement rescue plan if ≥120 (60%) but <180 (90%) participants are recruited into the study, and STOP if <120 (60%) participants are recruited into the study.

Setting

Participants are recruited from general practices, children's centres and other appropriate community venues in areas with a high South Asian population across different locations in the UK (North-West, Yorkshire, Midlands, London and Glasgow). Local principal investigators lead the conduct of the trial in each location, and are supported by the ROSHNI research team, all of whom, including principal investigators, are trained in good clinical practice.

Study population

Participants are women of self-ascribed British South Asian origin who live with their infant(s) aged ≤12 months, have postnatal depression and will reside in the geographical area of the study for the duration of their participation.

Inclusion criteria

The inclusion criteria are as follows: self-ascribed British South Asian women as mentioned by the Office of National Statistics,[13] aged 16 years or older; living with their infant(s), who are aged up to 12 months; and meet the DSM-5 criteria for depression as confirmed by the Structured Clinical Interview for the DSM (SCID).[16]

Exclusion criteria

The exclusion criteria are as follows: diagnosed physical or intellectual disability that prevents participation in the trial, postpartum or other psychosis, or active suicidal ideation.

The exclusion criteria will not include ongoing use of antidepressant medication and earlier self-reported common mental illness, including prior postnatal depression. Medication use will be recorded in the baseline and follow-up assessments, and this information will be considered at analysis.

Recruitment

Potential participants will be approached via GPs, children's centres, baby clinics, community centres, pharmacies and other relevant locations. The study is promoted in each of these locations, using materials that have been produced as a joint collaboration with the patient group, and appear in English, Urdu, Hindi, Bengali, Gujarati and Tamil. Community contact has already been initiated through partnerships with voluntary sector organisations, and the research team has started regular liaison meetings with the local health visitors, GPs and children's centres, for study promotion. Specific inputs are also being taken from the community organisations related to trial design, recruitment methods and the intervention content.

Participating GPs send a letter to all 6-week postnatal British South Asian women informing them about the trial and inviting them to take part. The letter includes the Patient Health Questionnaire 9 (PHQ-9),[17] a participant information sheet (PIS) and a response slip. Potential participants are asked to complete the PHQ-9 and consent-to-contact form, and return these to their local study site via pre-paid envelope. Postal and telephone reminders are sent to those who do not respond. In addition, GP records are monitored for non-responders so that primary care staff can remind women about the study at routine appointments. When the PHQ-9 and consent-to-contact forms are completed and returned, the research assistants will then make contact and arrange to speak to the participant in a convenient location, to provide further detail on the study and take consent.

Potential participants are also identified by the research team via GP case records. With the GP's permission, identified mothers are contacted either directly by phone or in person, by a clinical support officer, research nurse or GP administration staff, with the support of a bilingual member of the research team. To further ensure efficient recruitment, the research team visits local children's centres, baby clinics and other relevant locations, where potential participants are invited to take part and are provided with a PIS. Women who fulfil trial eligibility criteria are invited to provide written informed consent for trial participation and baseline assessment. All participants will be given ample opportunity for clarifications and time to consider before signing the consent form. The research team will advise participants that their participation in, or departure from, the trial does not affect any aspect of their usual care. Once a patient has agreed to participate and signed a consent form, they are then asked to complete the PHQ-9. Participants who score ≥10 are eligible to progress to the second

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stage of assessment of eligibility. Mothers who score <10 on the PHQ-9 at first screen will be again invited for a further assessment after 12–16 weeks to complete the PHQ-9 again, if within the 52-week postnatal period, to ascertain that later-onset postnatal depression is not missed.

The second stage of recruitment/assessment of eligibility is an interview with the SCID.[16] This is administered by trained members of the research team at baseline to confirm the diagnosis of depression. The SCID is a semi-structured interview that consists of standardised diagnostic questions arranged in modules corresponding to each DSM-5 Axis.[16] The SCID has been used in a large RCT of psychological intervention for postnatal depression with a multicultural population in Canada.[18] The PHQ-9 has been translated and validated in Urdu.[19] In cases where the SCID confirms depression, women are asked to confirm consent to take part in the study. In cases where the SCID does not confirm depression, these women are not randomised.

Our previous experience of research with British South Asian mothers who have postnatal depression indicates that engagement with participants' families is fundamental to success, and that this should begin at the time of screening. Therefore, at the potential participant's discretion, researchers will share details of the study with other family members. Contact details will also be provided for a bilingual senior investigator who will be available to converse with the family if needed. The first study participant was recruited on 8 February 2017.

Randomisation

Participants are randomised via an independent remote telephone randomisation service based at the Manchester Clinical Trials Unit. PHP is based on groups of between five and nine participants, and randomisation is stratified by centre and will use a block size of 10–18, depending on the size of the site, so that five to nine participants are allocated to PHP plus TAU and five to nine participants are allocated to TAU only. All efforts are made to ensure that the time period between baseline assessment and randomisation will be no longer than 4–6 weeks. The GP is informed about their patient's participation in the trial and treatment allocation by a letter, to be kept with the participant's medical notes.

It is not possible to blind participating mothers, their GPs or practice health visitors to treatment group. Researchers who are blind to treatment allocation will collect the outcome measures. To minimise selection bias and maximise external validity, we will recruit mothers across geographies in the UK and aim to keep the exclusion criteria to a minimum.

Intervention

PHP is a manual-assisted, culturally adapted, group psychological intervention delivered by two trained, bilingual facilitators (one lead facilitator and a co-facilitator). PHP is based on the principles of CBT, and has been found to be acceptable by participants in previous studies of postnatal depression in British South Asian women.[10] In ROSHNI-2, 12 group PHP sessions are delivered in total; sessions are delivered once a week for the first 2 months, and then fortnightly for the following 2 months. Each group session lasts 60–90 min, and at the start of each session participants are reminded about confidentiality and are assured by facilitators that any disclosures they make will remain confidential, with the exception of any intentions of harming oneself or others. The sessions covered within the PHP include identifying the pressures and expectations of being a South Asian woman, understanding and managing self-esteem, 'keeping up with the Chaudhry's', exercise and looking good, religion and spirituality, relaxation and 'taking time out', assertiveness and confidence building, breaking social isolation and building social networks, and practising CBT techniques and assessing change and developing relapse prevention plans.

The processes through which PHP was culturally adapted are described in detail elsewhere.[10,12] The PHP manual is available in English, Urdu, Hindi, Bengali, Gujarati and Tamil. Before each group starts, facilitators are matched to groups according to languages most commonly spoken by group participants. All facilitators are fluent in English and one or more of the study languages. Our earlier findings point out that when working with diverse populations, the venues where the intervention is delivered should be kept as neutral as possible and 'not owned' by a specific ethnic or religious group.[10] Therefore, PHP is delivered at children's centres and other community venues, as these are considered more acceptable to the British South Asian community than going for 'therapy' or 'treatment' in a medical setting. Transportation, child care and refreshments are provided to facilitate mothers' attendance at group sessions. Health Research Authority guidance states that payment to participants in therapeutic research, in addition to reimbursement, are permissible, as they may reduce potential power imbalances by making participation seem less like a favour to a healthcare professional or researcher.[20] Furthermore, in the UK it is standard practice to pay healthy volunteers and patient volunteers, therefore not paying others who also contribute to research would be unfair, and the benefits that participants may receive from the intervention do not mean that they should be barred from receiving payment. Participants are reimbursed with a £10 'love2shop' voucher for their time and their travel expenses are also reimbursed. The intervention group will continue to receive routine assessment and management by the primary care team. With the written informed consent of participants, a few groups sessions are recorded for quality checks.

Training, supervision and competency assurance

PHP facilitators are of different backgrounds and have varying levels of experience of delivering psychological interventions in the British South Asian community. Each facilitator received two full days training, which is delivered by PHP trainers who are mental health professionals and therapists by background (K.L., N.A.). The content of each PHP session is covered during training, and time is also spent on non-therapeutic specific skills, including engaging with participants, controlling PHP groups, listening skills and safeguarding. Didactic and Socratic teaching methods are used in PHP training and these are facilitated with presentations, group discussions and role-play methods. At least one out of 12 sessions is observed by PHP trainers, following which constructive feedback is provided and any areas that need improvement are highlighted. Monthly supervision is conducted by the PHP supervisory team and is available between sessions if deemed necessary by PHP trainers or requested by group facilitators. Supervision is conducted over the phone or via Skype in most instances, to account for the geographical distribution of groups and facilitators.

Treatment as usual

TAU includes participating GPs carrying out routine assessment and management and may involve ongoing monitoring, Improving Access to Psychological Therapies/other services referral and antidepressant prescription.

Outcome measures

Outcome measure data is collected at two time points: the end of intervention at 4 months, and 12 months after randomisation. The SCID is not repeated at the 4-month follow-up as it is used only as a diagnostic measure in ROSHNI-2, to establish diagnosis of depression (Table 1 and Fig. 1).

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Table 1 Schedule of assessments

Procedures	Visits (insert visit numbers as appropriate)			
	Screening	Baseline	4 months (end of intervention)	12 months
Informed consent	X			
Demographics		X		
Socioeconomic data		X		
Study assessments				
PHQ-9		X	X	X
HRSD		X	X	X
SCID		X		
GAD-7		X	X	X
EQ-5D		X	X	X
Parenting Sense of Competence scale		X	X	X
Social functioning		X	X	X
IAPT Healthy Minds Patient Experience Questionnaire			X	X
EPQ		X	X	X
Ages and stages questionnaires		X		X

PHQ-9, Patient Health Questionnaire 9; HRSD, Hamilton Rating Scale for Depression; SCID, Structured Clinical Interview for the DSM; GAD-7, Generalized Anxiety Disorder-7: IAPT, Improving Access to Psychological Therapies; EPQ, Economic Patient Questionnaire.

Primary outcome measure

At the 4-month follow-up, the primary outcome measure is the HRSD,[15] which is a valid and reliable measure of severity of depression. A score of ≤7 on the HRSD will indicate remission/recovery from depression.

Secondary outcome measures

Secondary outcome measures are as follows:

(a) Treatment response will also be measured with the HRSD; treatment response criteria is a reduction of ≥50% in the HRSD baseline score of the participants.
(b) PHQ-9[17]: valid and reliable self-report measure of severity of depression; Urdu and Bengali versions of the PHQ-9 have been validated.[21]
(c) Generalized Anxiety Disorder-7 (GAD-7)[22]: a valid and reliable self-report measure of severity of anxiety; an Urdu version of the GAD-7 has been validated.[23]
(d) Parenting Sense of Competence[24]: a valid and reliable self-report measure of parental competence;[25] Parental competence is measured on two dimensions of satisfaction and efficacy; the questionnaire has 16 items (nine on satisfaction and seven on efficacy) and is scored according to a six-point Likert scale, ranging from '1, strongly disagree' to '6, strongly agree'.
(e) Social functioning[12]: a self-report measure rating difficulty in completing ten items concerning daily function; the questionnaire is scored according to a five-point Likert scale, ranging from '0, no difficulty' to '4, often can't do the task'.
(f) Improving Access to Psychological Therapies Patient Experience Questionnaire[26]: a valid and reliable self-report measure of an individual's experiences of the intervention they participated in.
(g) Ages and stages questionnaires[27]: a valid and reliable parent-completed measure of childhood development; this series of 11 questionnaires each include 30 closed questions on five domains of child development; mothers will finish the questionnaire both at baseline and 12-month follow-up.
(h) EQ-5D-3L:[28,29] a health status measure, which has five dimensions (mobility, self-care, usual activity, pain/discomfort, anxiety/depression); participants can rate themselves as having no problems, some or moderate problems or extreme problems (for pain/discomfort and anxiety/depression domains), or unable to do an activity (self-care and usual activity domains or confined to bed (mobility domain).
(i) Economic Patient Questionnaire (EPQ): health service use will be captured using an EPQ; in addition to the National Health Service (NHS) and social care, cost to the participant for services will also be collected; if women in either arm of the trial are receiving any other treatment, this information will be captured here.

All measures are available in Urdu, Hindi, Bengali, Gujarati and Tamil.

Sample size

We will recruit 720 participants and randomise 360 into each arm. With 40 closed groups of nine and 360 controls, the trial will have 90% power to detect a clinically important difference between a 55% recovery rate in the intervention and a 40% recovery rate in the control, assuming an intraclass correlation (ICC) for group treatment of 0.05, a 75% follow-up and a 5% significance level. The sample size calculation and data analysis take into account clustering because of the partial nested design. Statistical methods for the partially nested design have been discussed in other publications.[30] Peer-reviewed work by scholars evaluating psychological treatments for postnatal depression points out that for the effect to be considered clinically meaningful, there needs to be a 20% absolute decrease in the number of mothers with depression post-treatment, endorsing the need to develop and implement such treatments. On the recommendation of the funding panel, we will be powered to detect a difference of 15% in the primary outcome between the two randomised arms. Our exploratory trial suggests that a 75% follow-up rate can be achieved at 4 months. Assuming this follow-up rate and an initial group size of nine women per group, the mean group size will be 6.75 women.

There is not enough reliable data related to the magnitude of therapy group clustering when evaluating psychological treatments for postnatal depression. Barrowclough et al give 30 estimates of the ICC for a group therapy, ranging from 0 (95% CI 0–0.29) to a maximum of 0.257 (95% CI 0.02–0.67), with a mean of 0.044 and median of 0.[31] From the width of the confidence intervals, there is appreciable uncertainty regarding these estimates. An ICC of 0.05 approximates to a moderate Cohen effect size (0.5) and this is close to the mean of the estimates from Barrowclough et al.[31] The study is robust against larger values of the intracluster correlation for group treatment. For example, if the intracluster correlation coefficient is as large as 0.1, power will still be 86.7%. We therefore believe that the value of 0.05 is a reasonable choice of ICC to use for sample size calculation. In some smaller sites, to reduce the wait for participants for PHP groups to start smaller PHP groups with five to six (10–12 SCID-positive) participants may be run. Reducing the group size to an average of five participants and recruiting a larger number of groups would further increase the power to 91%.

Statistical analysis

We will use intention to treat analysis. Statistical analysis will be carried out with a logistic random effects model to estimate the odds ratio of recovery between treatment arms, with additional covariates of centre, baseline severity of depression and education (<8

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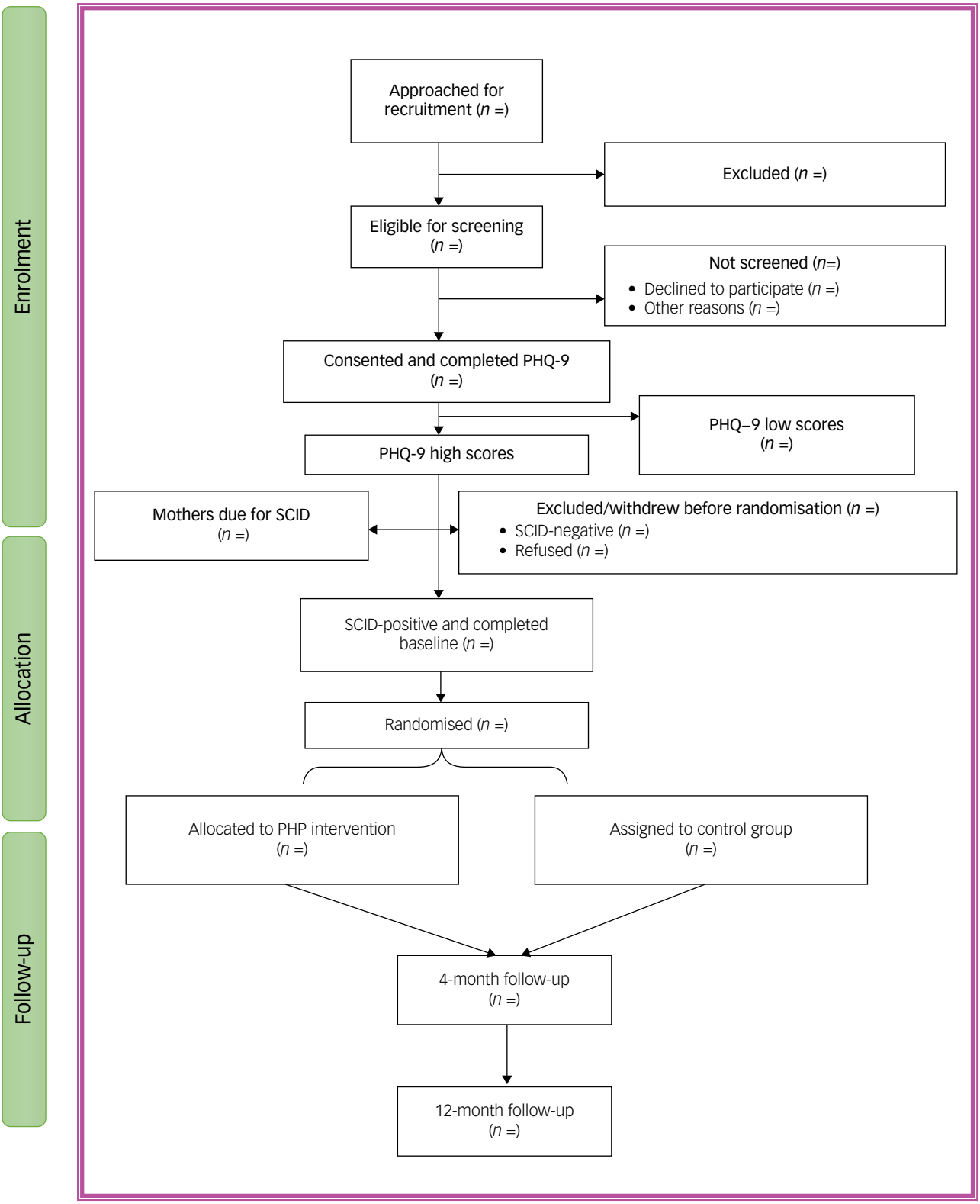

Fig. 1 Consolidated Standards of Reporting Trials study flow diagram.

years, ≥8 years). The analysis will be used for both the primary outcome measure (recovery at 4 months, end of intervention) and the further outcome (at 12 months). Random intercepts will be included for the therapy groups, with control participants treated as clusters of size 1, using the methods described by Roberts and Roberts[30] for the analysis of a partially nested trial.

The treatment effect for quantitative secondary outcome measures will be estimated with a similar approach, with a linear random effects model and a random intercept for therapy group. Baseline value of the measure, centre, parity and educational level will be included as covariates. Statistical analyses will investigate baseline factors that predict non-response by using a logistic

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random effects model, as non-response may be clustered by therapy group. Sensitivity analysis will be carried out under a range of assumptions regarding missing data informed by the analysis of non-response.

Economic evaluation

Measurement of resource use and costs

The primary economic analysis will use the perspective of the UK NHS and personal social services,[32] and costs will include those associated with use of NHS and social care primary, secondary and community based services. We believe that direct costs are mainly related to the use of in-patient, out-patient and clinic services at the beginning of the trial and related follow-ups. Sensitivity analysis will take a broader cost perspective to include voluntary care services as well as patient and family expenses. An EPQ data collection tool developed by the applicants will be used to collect service use data. A similar form has been used in an earlier completed trial of complex behavioural and psychological interventions in mental health.[33] All participants will be asked to complete the EPQ at enrolment and every follow-up assessment. Details to be collected include whether the participant has been admitted to psychiatric or non-psychiatric in-patient care or whether they used out-patient hospital services, including the names of the hospitals attended. The gathered information will be used to identify the relevant hospitals and patient records to extract more details of each admission and resource use by the participants. The EPQ will also ask for other non-hospital based health and social care and third sector services use by participants. Information related to any additional support from faith healers and Imams, and any out-of-pocket spend, will also be collected.

To calculate the cost of each component, national unit costs will be used and each item of resource use will be multiplied by the unit cost specific to that item. Hospital services will be costed by using the relevant national reference costs for each type of admission data published annually by the Department of Health.[34] Unit costs for medications will be obtained from the British National Formulary. Other sources of unit costs for other services will be based on unit costs of health and social care published annually by the Personal Social Services Research Unit, University of Kent.[35]

Measurement of health outcomes

The measure of health benefit for the primary economic analysis will be QALYs estimated from the EQ-5D-5L. The EQ-5D-5L is a validated, generic health status measure, designed to compare health outcomes across diseases. The National Institute for Health and Care Excellence recommends the QALY and the EQ-5D-5L as measures for economic evaluations.[32] The EQ-5D-3L responses will be used to generate utility values for each assessment. The economic analysis will use the value set for the UK general population, since alternative value sets relevant to South Asian populations are not available.[36] The utility scores for each participant from baseline to the end of follow-up will then be used to calculate QALYs as follows:

$$\text{QALY} = \Sigma[(U_i + U_{i+1} + U_{i+2})/3] \times (t_{i+2} - t_i) \text{ over } i = 0 \,\&\, 1,$$

where U is utility and t is time at assessment. The time between assessments is the time from baseline to 12-month follow-up ($i = 2$).

Cost-effectiveness analyses

The cost and health benefit data will be analysed by treatment allocated and include data for all participants whether or not they completed planned care. However missing data are inevitable from loss to follow-up or missing observations. Single imputation will be used for missing baseline measures of cost, utility and clinical indicators,[37] but not missing demographic data. An indicator for missing demographic data will be used.

The final imputation strategy will depend on the pattern of missingness in the data. If the data approximate missing at random or missing completely at random, multiple imputation from available data will be used, as recommended by Faria et al.[38] Literature review and regression analysis of pooled data (masked to treatment allocation) will be used to identify key baseline and follow-up variables associated with costs and QALYs to include in the imputation models. The data will be imputed by category of cost and EQ-5D domain to make best use of available data.

Primary analysis

Descriptive analyses of costs and summary health benefit measures will be reported for the intervention and comparator for the complete case and imputed data at baseline and follow-up assessment points. Regression analysis will estimate net costs and QALYs of the intervention. Covariates to account for factors that influence costs or QALYs will be identified from published literature, supplemented with analysis of pooled baseline data.

The regression-based estimates of costs and outcomes will be bootstrapped to replicate 10 000 pairs of incremental cost and QALY outcomes of the intervention. The distribution of pairs of net costs and QALYs will be plotted on the cost-effectiveness plane.[32]

Incremental cost-effectiveness ratios estimate the net cost per QALY gained by an intervention, and raise the question whether that cost is worth paying. To address this, the ICERs are compared with how much decision makers may be willing to pay for an additional QALY. However, the UK has no universally agreed cost-effectiveness threshold. The National Institute for Health and Care Excellence[39] has previously suggested a threshold of £20 000 to £30 000 per QALY. However, other commentators suggest this may be lower.[40,41] Reflecting this lack of consensus, the monetary value of simulated QALYs will be estimated across the range of £0–£30 000 willingness-to-pay thresholds. This recognises that decision makers may not be willing to pay for an additional QALY (in other words, they may only seek the lowest cost option) or could be willing to pay up to £30 000 for an extra QALY gained. To estimate the likelihood the intervention is cost-effective for the primary analysis, a willingness-to-pay threshold of £15 000 (the mid-point of the £0–£30 000 range) will be used.

Cost-effectiveness acceptability curves will be generated to show whether the likelihood that the intervention is cost-effective at each willingness to pay value is above 50%. As decision makers increase what they are willing to pay for an extra QALY, the additional health benefits from an intervention become more valuable, and it achieves net benefit in a bigger proportion of the 10 000 replicates.

Sensitivity analyses

Sensitivity analyses will be conducted to assess the effect of structural uncertainty introduced by the design of the economic evaluation. These analyses include re-estimating the results, using the primary clinical measure as the measure of health benefit; different approaches to missing data, such as use of complete cases only, or indicator values; broader cost perspective; and predictions of costs and QALYs beyond the 1-year trial horizon (for example, over longer time horizons of 5 and 10 years).

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Qualitative process evaluation

Although RCTs are the gold standard for establishing the effectiveness of complex interventions such as PHP, quantitative data does not provide insights into how complex interventions might be replicated or insights into how these interventions are experienced by patients. Process evaluations investigate the 'reach' of interventions.[42] Exploring the mechanisms through which interventions bring about change is crucial to understanding how the effects of the specific intervention occurred, and how these effects can inform the development of similar future interventions.[43]

To learn lessons for recruitment and acceptability of the intervention for the full trial, during the internal pilot phase of the trial, we will examine barriers to recruitment and retention and also look at personal experiences of the women who withdrew from participation in the trial. We will invite women and PHP facilitators to participate in a semi-structured interview.

In the full trial (following successful completion of the pilot), we will conduct interviews with women who have completed the intervention to explore acceptability of the PHP, and women who enrolled in the trial but only attended one or none of the PHP sessions. We will interview group facilitators who have delivered the PHP intervention, and GPs who have engaged with, and referred women to, the ROSHNI trial, Semi-structured interviews will be utilised to explore views on the perceived feasibility, acceptability and sustainability of the PHP in the management of postnatal depression, in this patient group, in primary care.

Topic guides have been developed for the pilot phase by the research team following review of the literature and discussion with patient and public advisors, and will be iteratively developed and refined during the pilot and then in the main trial as analysis progresses.

The objectives of the qualitative study are to explore early barriers and enablers to study participation, to optimise ongoing trial recruiter training and trial recruitment rates (pilot); identify reasons for continuing or not continuing with the study (pilot and full trial); examine the acceptability of the group intervention from the perspective of British South Asian women (pilot and full trial); explore views of the GPs on the group psychological intervention and its impact on practice (full trial); and explore perspectives of group facilitators (group psychological intervention deliverers) about training and delivery of the intervention (pilot and full trial).

Participants are given information about the qualitative aspect of the trial during the baseline assessment and also asked for consent to being contacted by the research team to participate in an interview. Perspective interviewees are identified via a purposive sampling strategy, and to achieve the purpose of inviting patients from different socioeconomic backgrounds, ages and native languages, maximum variation sampling techniques are used and patients are sampled from across the five centres for the trial. Interviews are conducted with women once the primary outcome measure has been obtained (4 months post-randomisation) so as to avert bias likelihood that might be introduced by the supportive role of the qualitative interview. Participant interviews will be conducted within 8 weeks of their primary outcome measures being collected.

In the full trial, up to 20 women who participated in the group sessions will be interviewed with the aim of examining at length the acceptability of group meetings, viewpoints on discussing personal problems in front of other participants, views on the involvement of the group facilitator, family's perspective on the participants' attendance and the effect on the current situation. Interviews will also be conducted with up to 20 women who dropped out of the study after one or no session, to better understand their reasons for not continuing with the sessions.

Interviews will also be conducted with group facilitators (up to 15) to investigate barriers and enablers to the group work. GPs participating in the trial (up to 15, across study sites) will be invited to participate in interviews to further our understanding on the management of British South Asian women with postnatal depression and the impact of the intervention on routine practice work.

The researcher will contact the trial participants, GPs and group facilitators, check consent, and arrange an appointment to interview them at a time and place convenient to the respondents (e.g. home, telephone, general practice). Before the face-to-face or telephone interviews, written consent to participate in the interview will be obtained. Telephone interviews, lasting up to an hour, will be conducted with suitable equipment and infrastructure. The researcher will obtain consent from the participant to record and transcribe verbatim the interview. Where the participant does not speak English as their first language, interviews will be carried out in the participant's preferred language and later translated for analysis. Existing recommendations for conducting and reporting cross-language qualitative research will be used where applicable,[43] including pilot testing the interview guide translation before carrying out the interview, independent verification of translated interviews, and detailing the role and credentials of the translator in any outputs.

Data analysis

Thematic analysis with principles of constant comparison[44] will be conducted. This will be followed by framework analysis, which allows for the inclusion of *a priori* as well as emergent concepts.[45] Framework analysis is effective for using data collected through open-ended questioning and focusing it toward a particular research question in health services research, particularly when a large body of data has been generated.

There are five phases of the framework method of analysis, which are interlinked to form a rigorous framework: familiarisation with the data; identifying a thematic framework; indexing; charting; and mapping and interpretation. These phases enhance understanding and interpretation of the data from descriptive accounts to a conceptual explanation.[45,46]

The framework analysis will be sensitised by the use of the theoretical framework of acceptability.[47]

Regular meetings between the three researchers (S.A., R.M. and J.B.) who are responsible for independently carrying out data coding, and their supervisors (C.A.C.G. and P.Bee.) will be organised to ascertain that the emerging codes remain grounded in the original data.

Public and patient involvement and engagement

Patient and public involvement and engagement was of great benefit to the recruitment and retention strategies used during the ROSHNI-D trial, and for dissemination.[12] As such, patient and public involvement and engagement activity is planned throughout the trial.

Initial discussions with key stakeholders from institutions to hold workshops in temples, gurudwaras, mosques, churches, and children's and community centres were held so that we can further community engagement. Workshops provide information on depression in general, and particularly postnatal depression in British South Asian women. We record and take into account feedback from workshops, with particular focus on how to address stigma. The advisory group members provide a crucial support when it comes to community engagement. The advisory board also engages patients with trained expertise in research methods and have trained over 50 patients and carers in research methods.

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Seminal work by Lovell and colleagues has a good practice citation by the National Institute for Health and Care Excellence.[48]

Ethics

The research team brings with it an enriching clinical and research experience, and has hands on training in managing challenging situations in research interventions and interviews. We are cognisant of the fact that some respondents can be vulnerable, therefore we will make sure we provide adequate supervision of the researchers, keeping in mind safeguarding participants' welfare. Timely and regular supervision will be carried out during the entire course of the project for all research staff and group facilitators, including training the staff in good clinical practice and safeguarding (study ethical approval number: IRAS 187851).

Clear guidelines relating to a distress policy have been formulated, keeping in mind the potential effects of conducting research with this group. A distress policy has been formulated. A number of practical measures are taken to minimize distress and risk to participants; for example, when obtaining consent, researchers clarify to participants that they are able to take time in answering questions.

Monitoring, recording and reporting of adverse events will be managed with the local principal investigator, the participant's GP and health visiting team, and in line with each Trust's policy. The Clinical Trials Unit will carry out audits and safety monitoring. Safety protocols have been designed and developed to ensure that safety of research staff, participants and their families remain safe when making contact, conducting research and afterward. This includes researchers confirming that they are speaking with the participant and not leaving information with other household members, asking participants in qualitative interviews how they are feeling at the end, and signposting relevant support when necessary, and researchers following lone-worker policy.

Progress with ROSHNI-2 internal pilot

The internal pilot was designed to test the ability of the four additional centres to recruit to time and target, with a target recruitment of $n = 180–200$ patients within a 12-month period (November 2016 to October 2017), with a minimum of 120 patients for the trial to continue. Because of a variety of delays, all sites started late, and thus the recruitment period for the internal pilot centres was extended until June 2018.

Recruitment of more than the minimum 120 patients during the internal pilot up to 30 June 2018 was achieved, and the internal pilot target was met to ensure the study continued recruitment. Following the internal pilot, the decision was made to close one site and the resource saving to be redistributed to capitalise on the greater recruitment opportunity in other recruitment sites. The Glasgow site was not able to recruit sufficient number of participants because of low British South Asian birth rates.

Summary

This study is unlike other comparable mental health studies or even physical health trials with British South Asian participants, given the stigma of mental health in the different South Asian communities and the difficulty in engaging young women, particularly in households often dominated by men and older people. Each site requires its own culturally adapted approach for community engagement and not just one approach. Despite its challenges, the internal pilot study has been successful in demonstrating the viability of progression to a full trial by ensuring that trial processes relating to recruitment, randomisation, treatment and follow-up assessments now work well. In addition, the value of the internal pilot period has been recognised in reflecting on lessons learned. This allowed us to improve the management, communication, processes and efficiency of all trial activity, thus optimising outputs of all remaining centres as we moved into the full trial.

Dissemination

The results of the study will be published in peer-reviewed journals and presented at national and international conferences. Study findings will also be disseminated to local and national groups in partnership with patients, carers and local voluntary organisations such as MIND, Ethnic Forum and Social Action Forum. Results will also be publicised through a website, short films and our media partners, including Pendle Radio and Asian Image, and through local temples, mosques, churches and community centres, using our existing networks such as the Black and Minority Ethnic Network Lancashire. Information about the research will also be disseminated to the British Council, which has extensive networks not only within the UK, but also overseas.

We will also take advantage of our expertise in working with the NHS and voluntary sector, and share the training needs and information of the culture specific needs of this group. Extensive consultation rounds related to the rich knowledge gained from the trial will be shared with NHS stakeholders and with relevant local, regional and national policy makers and commissioners, to better inform decision-making and service improvements. Consultations will also include patients from the local communities and trial participants. A low-cost PHP manual and how-to 'tool kit' will be a crucial output of the study.

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Data availability

The data that support the findings of this study will be available from the corresponding author, N.H., upon reasonable request, following the data lock, analysis and publication of findings.

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Author contributions

All authors have contributed to the protocol development and approved the final version of this protocol paper. N.H. is the study chief investigator with overall responsibility of the study. S.A. and J.B. are the study trial managers. F.L. was part of the exploratory phase of this trial, contributed to the submission of the bid and is now a deputy manager on the project. N.B. is the lead research assistant and contributed to the development of study promotional materials and study design and methodology. N.Z. is the data manager on the project and has contributed to the data management plan and statistical analysis plan. S.S. is an expert by experience and researcher on the trial. N.S. is a patient researcher who was a participant on the trial in its exploratory research for patient benefit phase and then has gone on to support the development of the bid, design of study materials and is part of our trial steering committee. C.A.C.G. and P.Bee are the qualitative research methods leads. R.E. is the study trial statistician. K.L. is the lead for supervision of the intervention training and delivery. R.M. is the site lead for the Midlands, supported by T.B. and J.K. I.M. and K.B. are the site leads for London. C.W. and J.M. are site leads for Glasgow. N.S. is the site lead for Yorkshire. A.I. and N.G. are research assistants supporting logistics of trial delivery including preparation of study materials, community engagement, planning, and monitoring. N.M. is a service user by experience contributing patient and public involvement and engagement input through the trial. J.N. is resposible for intervention delivery and community engagement. P.Bower, P.Bee, N.S., L.D., A.R., S.R. and W.W. are co-applicants. T.S. is a health economist.

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Declaration of interest

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare no support from any organisation for the submitted work. N.H. is Chair of the Board of Trustees at Manchester Global Foundation; a charitable incorporated organization. He was former trustee at Lancashire MIND, Abaseen Foundation and Pakistan Institute of Living and Learning. N.H. is an NIHR Senior Investigator. S.R. has received grants from Janssen, Otsuka and commercial companies outside the submitted work. P.Bower. reports other grants from NIHR during the conduct of the study. N.S. was a former patient in the exploratory phase of this trial. K.B., a member of the *British Journal of Psychiatry* Editorial Board, but did not take part in the review or decision-making process of this paper. All authors declare no other relationships or activities that could appear to have influenced the submitted work.

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ROSHNI-2 – Using a culturally adapted model of recruitment, engagement and retention to mental health research for British South Asian Women experiencing symptoms of Postnatal Depression

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Key Messages

(1) The rates of postnatal depression in British South Asian women are high.
(2) Postnatal depression (PND) is known to cause disability and suffering in women and negative consequences for their infants and their family.
(3) Due to linguistic and cultural barriers, South Asian women do not access health care services. This is a major contributor to ethnic inequalities in access to appropriate mental healthcare.
(4) Mothers from South-Asian backgrounds (Bangladesh, Pakistan, Sri Lanka and India) represent a very large number of births in the participating study sites.
(5) There is a growing concern about ethnic disparities in the provision and access to PND services. Increasing for PND access is an identified priority in the UK.

ROSHNI-2: Multi-Centre Randomized Controlled Trial (RCT) of a group psychological intervention for postnatal depression in British mothers of South Asian origin. The research project has been funded by the National Institute for Health Research (NIHR-HTA) (14/68/08) and Lancashire and South Cumbria NHS Foundation trust is the sponsor for this study.

- The primary objective of the project is to evaluate the clinical and cost effectiveness of a culturally adapted group psychological intervention (Positive Health Programme, PHP) in primary care for British South Asian (BSA) women with postnatal depression compared with routine treatment.
- The secondary objective of the study is to evaluate the impact of the PHP intervention on secondary outcomes (health status and quality adjusted life years, parenting competence, social function, anxiety, satisfaction with care) compared to routine treatment.
- ROSHNI means light in Urdu Hindi language

This paper will present a description of recruitment, engagement and retention of British South Asian women to the study. It also reports some challenges faced in study set up and factors to be considered when working with this specific community. The study closed to recruitment in March 2020 and the final outcome assessments will be collected in Feb 2021. The final study reports will be published in June 2021.

The prevalence of common mental disorders varies noticeably in the different Black and Asian Minority Ethnic (BAME) communities. The rate of anxiety and depression in British South Asian women (63.5%) is higher compared to white women (28.5%) [1]. There are different pathways and methods in the use of mental health services (Morgan et al., 2005; Bhui et al., 2003). In general, people of ethnic minority backgrounds are less likely to contact their general practitioner (GP) about mental health issues compared to their white British counterparts.

Our work across many years in this population both in the UK and in South Asia suggests a number of barriers which may contribute to the disparities in accessing mental health services. These barriers include cultural, institutional, linguistic and socioeconomic exclusions that may marginalise people from the BAME community. Reports and literature since many years have highlighted that these hard-to reach-groups are less likely to have access to appropriate mental healthcare (Suresh & Bhui, 2006). Cultural competence is one such important barrier to accessing services,

Pictures from various community events including marking international women's day and celebration of completion of PHP sessions

i.e. the ability of providers and organisations to effectively deliver healthcare services that meet the social, cultural and linguistic needs of patients (McLean, Campbell, & Cornish, 2006; Dowrick et al., 2009), variation in clinical practice and service provision, cultural explanatory models of illness; stigma (Suresh & Bhui, 2006; Knifton et al., 2010; Gary, 2005).

There is limited research conducted on understanding these barriers that BAME communities face in accessing appropriate services. Despite the huge need within this community, research has not appropriately captured what factors make this a "hard-to-reach" community. Clinical Research Networks and Research departments across the study centres have been hugely helpful in supporting the study; however, they struggle to engage in working across cultures and languages due to lack of multilingual staff and staff trained in engagement across diverse populations.

The Positive Health Programme (PHP) is a culturally adapted group CBT based intervention for PND (Husain, Lovell, & Chaudhry, 2014; Khan et al; Turner, Chew-Graham, Folkes, & Sharp, 2010) that has been developed by our research group. An exploratory randomised controlled trial (RCT) (Exploratory RCT of a group psychological Intervention for Postnatal Depression in British Mothers of South Asian Origin – ROSHNI-D) (Husain, Lovell, & Chaudhry, 2014), was conducted across Manchester and Lancashire (UK), and provides evidence for the feasibility and acceptability of the present trial. The number of mothers screened (n=615) and trial retention figures at the end of the intervention (79%) highlight the ability of the research team to engage with the population (Masood et al., 2015)

METHODS

Design. This is a multi-centre, two-arm; rater-blind randomised controlled trial comparing PHP and Treatment As Usual (TAU) with TAU only for British South Asian women with PND. Outcome assessments are collected at end of intervention (4 months) and 12 months post randomisation.

Participants. British South Asian women who have a child aged 12 months and under, living within the geographical area of the study, were invited to participate in the study. We recruited participants (n= 733) from various venues including general practices, children's centres and other appropriate community venues in areas of high South Asian density across the study centres (NorthWest, Yorkshire, Midlands and London).

Recruitment Strategies. *Primary care* – we recruited participants with the support of GP practices and health visiting teams. Potential participants were approached via GP or HV referrals; research assistants attended immunisation and baby well-being clinics where they were able to approach and discuss the study. The GP practices also carried out searches on their clinical systems to identify lists of potential participants and either a letter or call was made to inform the potential participant that the study is ongoing with support from the practice.

Community venues – bilingual research assistants attended community children's centres or community venues that host children's playgroups. Across most of the study sites these replace what were previously "sure start" centres, due to funding restrictions most "sure starts" are now closed.

3rd sector voluntary organisations – We worked closely and developed service level agreements with a number of 3rd sector organisations across our study sites. The teams across the study centres have hugely benefited from these partnerships. We have been fortunate to have key organisations supporting our study promotion, raising awareness and recruitment to the study. Some organisations such as Ethnic Forum have provided community engagement officers, which have proved to be vital for the successful recruitment rates. This model of working has proven to be more efficient as we have faced some barriers in getting approvals, governance and access across sites. We collaborated with different organisations to host events involving families, key opinion makers from the local community and professionals to tackle stigma and raise awareness.

Many languages are spoken by the British South Asian population, the common ones being Urdu, Punjabi, Gujarati, Bengali and Tamil. Each researcher is able to speak English and one of the study languages fluently. Participants are able to communicate in the language that they feel most comfortable in. All the study materials were translated into the key study languages including promotional posters, information leaflets and study assessments.

Community engagement and social media. Mainstream pathways to recruitment may not always be accessible to all and therefore employing new strategies is crucial.

Social media – Over 3 billion individuals across the globe are actively using social media. We are using well-known platforms such as Facebook, Twitter, and Instagram to disseminate study information. A review of recruitment strategies along with the Patient, Public, Involvement

Pictures from site launch events and community events to mark maternal mental health day

and Engagement (PPIE) group resulted in major focus on recruitment efforts using social media. In comparison to recruitment rates prior to the social media campaign, increase in social media promotion and activity on our pages has resulted in a higher rate of recruitment including self-referrals to the study.

Chai with ROSHNI-2 – Inviting General Practitioners (GPs) & Health Visitors to meet the public and encouraging conversation around mental health over chai.

Screening drop in- Advertising drop-in sessions across Children's centres and G.P practices. These have been a popular method to provide opportunities for mums to participate, coinciding with the regular clinic appointments.

Challenges to study set up and recruitment. One of the key challenges in carrying out this project has been contractual arrangements such as letters of access and organisational barriers. In most high density British South Asian regions there is limited to no research done in health in general and mental health in particular. The process of initiating set up, to managing contracts and collaboration agreements and then actual recruitment via letters of access has in nearly all centres resulted in a minimum 3 month or more delay. These are valuable recruitment months and have a huge impact on not only the figures but also the trust and rapport building within the wider community. We have learnt from this and have put in steps to strengthen our research framework and study set up processes within the sponsor trust.

Progress to date. The study recruitment ended in March 2020. The study exceeded its recruitment target and has randomised 733 participants in total across the study sites. The table below shows recruitment figures by each centre:

Recruitment and Randomisations to ROSHNI-2

Site	*No. of mums screened*	*No. of high scoring mums (% of distress)*	*No. of mums randomised*
Northwest	2446	554 (22%)	336
London	1194	372 (31%)	288
Yorkshire	143	75 (52%)	60
East Midlands	407	87 (21%)	49

CONCLUSION

This study is not like other comparable mental health studies or even physical health trials with British South Asians, given the stigma surrounding the topic of mental health in the different South Asian communities and the difficulty in engaging young women. In particular, living in multi-generational households where decision makers are often the husbands or elderly family members such as the mother-in-law/father-in-law, may hinder participation. Each site requires its own culturally adapted approach for community engagement and not just one approach. Despite its challenges, the study to date has been successful in demonstrating a high level of recruitment and retention.

The experience of recruitment to this trial has resulted in multi-disciplinary conversations on a wider scale across the UK in relation to a culturally adapted method of engagement and delivery when working with "hard-to-reach" communities. The Black and Ethnic Minority community that is so often labelled as "hard to reach" has in fact been reported by one of our community partners as 'easy to ignore' because of the challenges in rolling out such projects and a lack of innovative and culturally sensitive recruitment strategies in place. It is important that researchers share their experience of such strategies and what works well in this community so that all voices can be heard.

Conflict of interest

NH is the chair of board of Trustees of Manchester Global Foundation. NH is the past Trustee of Lancashire Mind, Pakistan Institute of Living and Learning and Abaseen Foundation UK. NH has published work on culturally adapting and testing psychological interventions.

Disclaimer

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Efficacy of a culturally adapted, cognitive behavioural therapy-based intervention for postnatal depression in British south Asian women (ROSHNI-2): a multicentre, randomised controlled trial

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Summary

Background Postnatal depression necessitates timely and effective interventions to mitigate adverse maternal and child outcomes in the short term and over the life course. British south Asian women with depression are often underserved and undertreated due to stigma, language barriers, and cultural barriers. This trial aimed to test the clinical efficacy of a culturally adapted, group cognitive behavioural therapy (CBT)-based intervention, the Positive Health Programme (PHP), delivered by non-specialist health workers for postnatal depression in British south Asian women.

Methods This study was a randomised controlled trial, with culturally adapted recruitment and an internal pilot, comparing the PHP (intervention group) with treatment as usual (control group) in British south Asian women with postnatal depression. The study was conducted at five centres across the UK. Participants were aged 16 years or older, met the DSM-5 criteria for depression, and had infants aged 0–12 months. Randomisation (1:1) was stratified by centre, with a block size of 18, and was done through an independent remote telephone service. The PHP was delivered over 12 group sessions in 4 months. The primary outcome was recovery from depression (defined as a Hamilton Depression Rating Scale [HDRS] score ≤7) at 4 months after randomisation, and an assessment was also done at 12 months. Analysis was on an intention-to-treat basis including only participants with non-missing outcome data; we used a random-effects logistic regression model including fixed covariates for study site, baseline depression severity (HDRS score), parity, and years in education and a random coefficient for therapy group. This trial is registered with the ISRCTN (ISRCTN10697380).

Findings Of the 9136 individuals approached for recruitment between Feb 8, 2017, and March 29, 2020, 4296 women were eligible for and consented to screening, among whom 732 screened positive and were randomly allocated: 368 (50%) to the PHP group and 364 (50%) to the control group. Participants were mostly of Pakistani (397 [55%] of 719 with available data), Indian (176 [24%]), or Bangladeshi ethnicity (127 [18%]), with an overall mean age of 31·4 years (SD 5·2), with their youngest infants having a mean age of 23·6 weeks (14·2). At 4 months from randomisation, the proportion of participants who showed recovery from depression on the HDRS was significantly higher in the PHP group (138 [49%] of 281) than in the control group (105 [37%] of 281; adjusted odds ratio 1·97 [95% CI 1·26–3·10]). At the 12-month follow-up, this difference was no longer significant (1·02 [95% CI 0·62–1·66]).

Interpretation In British south Asian women with postnatal depression, a culturally adapted group CBT-based intervention could aid in quicker recovery from depression compared with treatment as usual. Further research is needed to identify how to sustain the treatment effect and establish strategies for scale-up.

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Introduction

Postnatal depression affects around one in eight women globally and typically presents within the first few weeks after giving birth.[1,2] It has substantial public health implications due to its association with several adverse outcomes in children, including impaired cognitive, socioemotional, and physical development.[2] Moreover, it contributes considerably to the intergenerational transmission of health and socioeconomic inequalities globally.[3–7] Common perinatal mental disorders, including postnatal depression, are associated with long-term societal costs; in the UK, for example, these costs amount

Research in context

Evidence before this study

Postnatal depression is highly prevalent worldwide, is associated with poor maternal and infant outcomes, and is a significant public health concern. The UK National Institute for Health and Care Excellence (NICE) recommends cognitive behavioural therapy (CBT) as a primary treatment for postnatal depression. Our previous systematic review and meta-analysis of 59 CBT-based interventions showed that group-based CBT interventions were effective for postnatal depression (standardised mean difference –0·67 [95% CI –0·96 to –0·38]; n=4915) in majority populations in high-income societies, even when administered by trained non-specialist health workers. It also showed a scarcity of studies on the acceptability and effectiveness of psychotherapeutic treatments for postnatal depression in women belonging to minority ethnic groups.

Added value of this study

This is the first large-scale randomised trial to test a group CBT-based intervention for postnatal depression in British south Asian women, a group that is underserved by psychological therapy services due to stigma and language and cultural barriers. Our previous exploratory work established the need for cultural adaptation of psychological therapies in the UK especially for south Asian ethnicities to improve access to care, engagement, and uptake. Based on these experiences, we developed a culturally adapted CBT-based approach, the Positive Health Programme (PHP), delivered by non-specialist health workers. Compared with treatment as usual (control), the PHP intervention was associated with a higher proportion of patients recovering from postnatal depression at 4 months after randomisation, suggesting that this intervention can aid in earlier recovery. However, no significant difference in recovery between the PHP and control groups was observed at 12 months.

Implications of all the available evidence

Minority ethnic groups are often excluded from mental health research and can be overlooked if services do not consider their cultural and social contexts. In addition to providing evidence of the feasibility and effectiveness of a culturally adapted, group CBT-based intervention for this population, the study demonstrates methodological approaches for engaging UK-based minority ethnic communities in mental health research. Outreach approaches and stakeholder and service user engagement can help to overcome some of the barriers to accessing services.

to approximately £8·1 billion for each 1-year birth cohort.[3] Bauer and colleagues suggested that the cost of enhancing services to address common perinatal mental disorders could be less than a fifth of the current societal costs associated with these conditions, thereby highlighting the need for improved interventions and support.[4]

Despite postnatal depression being acknowledged as a major public health concern, a substantial treatment gap still exists, whereby a large proportion of those with clinically relevant symptoms do not seek or are unable to access treatment—in the UK, for example, this proportion is as high as 60%.[3,4] Closing such treatment gaps is now a global priority.[8–11] Although progress has been made, considerable disparities remain in providing timely mental health care and addressing inequalities in access, experience, and outcomes.[12] These disparities are particularly pronounced for women from minority ethnic backgrounds, such as south Asian women, the largest minority ethnic group in the UK,[13–15] who, despite higher prevalence, present for mental health treatment at a considerably lower rate than White women. Innovative solutions and approaches are needed to enhance access to perinatal mental health services for minority ethnic groups.[15,16]

Guidance from the National Institute for Health and Care Excellence (NICE) in the UK recommends cognitive behavioural therapy (CBT) for the prevention and treatment of postnatal depression,[17] particularly for women with mild to moderate depression. Although the UK National Health Service (NHS) offers free to access CBT through the NHS Talking Therapies service (previously the Improving Access to Psychological Therapies [IAPT] initiative),[18] access to and acceptability of CBT among minority ethnic groups, especially south Asian people, remains low, both for postnatal depression and more generally.[19,20] Language barriers and ethnic and cultural beliefs can substantially hinder south Asian women's efforts to seek help during the perinatal period. There is, therefore, a pressing need for culturally appropriate models for the effective screening and care for postnatal depression in minority ethnic populations.[21,22]

Our earlier exploratory research identified the need for cross-cultural adaptation of psychological therapies, particularly among south Asian populations in the UK, to improve engagement and uptake.[20] Such adaptation requires not only an appreciation of cultural and linguistic needs, but also an understanding of the unique psychosocial risk factors (eg, family and intimate partner violence) and family dynamics within minority ethnic populations such as south Asian communities.[2] This research informed the development of a culturally adapted, CBT-based intervention: the Positive Health Programme (PHP).[19,20] In a previous feasibility study,[19] we showed that the PHP was feasible and led to improvements in postnatal depressive symptoms, quality of life, and marital relationships, and improved access to services for south Asian women.[19]

The primary objective of the ROSHNI-2 trial (*roshni* meaning "light" in Urdu and Hindi), informed by our

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earlier feasibility study,[19] was to investigate the clinical efficacy of the PHP intervention for postnatal depression in terms of recovery from depression in British south Asian women. Additionally, the trial aimed to examine the intervention's effect on secondary outcomes, such as postnatal anxiety, social functioning, quality of life, access to health services, parenting competence, and treatment satisfaction.

Methods

Study design

ROSHNI-2 was a partially nested, multicentre, randomised controlled trial that included an internal pilot study. The trial was conducted at five study centres (including general practices, community settings, and children's centres) in the UK with high south Asian populations, across northwest England, Yorkshire, the

Panel: **Key strategies used to facilitate recruitment**[21]

Community engagement

Bilingual research assistants attended community children's centres or community venues that host children's playgroups. We worked closely and developed service level agreements with a number of third-sector organisations across our study sites. These organisations had community link workers or outreach workers who were trained in study processes to provide information about the study and raise awareness in the community. This upskilled community workers and also ensured those with established community trust and rapport could positively influence study recruitment.

The team collaborated with different organisations to host events involving families, key opinion makers from the local community, and professionals to tackle stigma and raise awareness. Previous research staff and health professionals have labelled minority ethnic community members as "hard to reach", and thus the people in those communities are wary of working with big establishments.[19]

Chai **with ROSHNI-2**

The team arranged regular drop-in sessions open to the community. General practitioners and health visitors were also invited to meet the general members of south Asian community and encourage conversations around mental health in the postnatal period over *chai* (tea). The events were focused on normalising conversations and tackling stigma. Information about the study was given at the end of the events and anyone eligible was able to ask for more information.

Engaging with faith leaders

The team worked to liaise and engage with faith leaders from the key religions practised in this community. Faith leaders from Muslim and Hindu communities joined study advisory groups. Meetings were held with local councils of mosques and Hindu and Sikh associations. They were briefed on the importance and background of the study and asked to support by sharing information with their congregations about the study at events. Some mosques included information on ROSHNI-2 at the end of sermons during the holy month of Ramadhan and encouraged families to engage with the project.

Family engagement

There was a need for educating family members on taboo subjects such as postnatal depression and seeking support from health services in a manner that suited them. Many felt they needed to carry on as normal and not make their situation publicly known. Family members felt that if other people found out, family reputation might be affected. Some participants would not receive permission to attend the groups from extended family or their partner. The team offered to meet with the whole family to explore and discuss the content of the group sessions and the importance of the therapy sessions, not just for the mother but also for the child or children. Family were also included in the consent process to ensure that the team were being sensitive to the power dynamics within south Asian homes and facilitating participation by adapting processes.

Language

Many languages are spoken by the British south Asian population, the common ones being Urdu, Punjabi, Gujarati, Bengali, and Tamil. Each researcher is able to speak English and one of the study languages fluently. Participants are able to communicate in the language that they feel most comfortable in. All the study materials—including promotional posters, information leaflets, and study assessments—were translated into the key study languages.

Cultural competence and staff training

Staff were trained in cultural sensitivity and competence, including awareness of participants' cultural commitments and religious beliefs. Regular team discussions were held on dynamics, respect, understanding, and appropriateness of verbal and non-verbal communications. ROSHNI-2 staff researchers and also participants helped to raise awareness among non-minority ethnic health professionals of cultural differences, including by sharing positive case studies with general practitioners or health visitors.

Social media

Trained research assistants promoted the ROSHNI-2 project via social media platforms including Facebook, Twitter, and Instagram. Promotions included weekly updates and posts on the importance of maternal mental health. The pages were managed by a communications and media intern within the team in line with guidance from the National Institute for Health and Care Research on the use of social media in research. We produced short promotional animated videos, posts introducing members of the team to build trust and rapport within the community, and updates on study progress. Potential participants were able to message with questions or to express interest in participating.

East Midlands, London, and Glasgow. In the intervention group, participants were nested in therapy groups, while those in the control group were not. This rater-blind trial compares the use of the PHP plus treatment as usual with treatment as usual alone. The trial protocol, published previously, provides details about the study design and methods.[23] Recruitment included an 18-month internal pilot phase.

The Northwest Health Research Authority granted ethical approval for the research (approval number IRAS 187851; approval date Jan 6, 2017). The data monitoring and ethics committee collaborated with the trial steering committee to review the quality and safety aspects of the research. Our team developed a comprehensive risk policy to address concerns regarding potential harm to trial participants, especially in the context of the prevalence and stigma regarding mental health in the south Asian community. We followed the safeguarding policies of local NHS trusts to ensure the safety and wellbeing of participants, details of which can be found in our protocol.[23]

NS, a service user collaborator, served as a key member of the research team throughout the project, including during the proposal development stage, acquisition of ethical approval, implementation, and dissemination of results. To develop a comprehensive intervention and protocol, the study team also sought the participation of British south Asian women who had lived experience relevant to the study. Alongside NS, the advisory groups had patient and public involvement, with three individuals supporting the study.

Participants

Eligible participants were south Asian women who met the DSM-5 criteria for depression, were aged 16 years or older, and had an infant aged 0–12 months. Exclusion criteria were a diagnosis of postpartum or other psychosis, active suicidal ideation, and physical or intellectual disability that would limit the ability to provide informed consent. Participants taking antidepressant medication or with a history of common mental illness, such as previous postnatal depression, were not excluded.

General practice records were used to identify eligible participants, who received study invitation letters and consent-to-contact forms. Participants were also identified in children's centres, community venues, and through self-referrals. Screening was done using the nine-item Patient Health Questionnaire (PHQ-9). In women who scored 10 or higher on the PHQ-9, the research diagnosis of postnatal depression was confirmed using the Structured Clinical Interview for DSM-5 (SCID-5), administered by trained researchers. We adapted the PHQ-9 screening procedure from self-report to a standardised conversational approach to address inconsistencies in participant responses. This adaptation had the added benefit of fostering a more open dialogue, building rapport and trust, which led to more honest responses from the mothers

The study used various recruitment strategies (panel), placing a strong emphasis on establishing trust in the research team within the community through frequent discussions with key stakeholders about mental health and the importance of participation in research. Addressing the stigma associated with postnatal depression and increasing awareness about appropriate avenues of care was a key focus. Through various community-engagement activities, including clinic drop-in sessions and participation in health promotion events, the initiative sought to empower the community by highlighting the significance of their involvement in research as a means to drive change and help to address the community's specific needs. Staff training emphasised the importance of flexibility in scheduling, location, and language options, and also addressed the inclusion of family members and the need for adaptable measurement procedures to avoid creating barriers to participation. To maximise reach, trained research assistants actively promoted the ROSHNI-2 project on social media platforms (including Facebook, Twitter, and Instagram) in various south Asian languages, thus ensuring that the recruitment strategy was inclusive and wide reaching.

Randomisation and masking

Eligible consenting women were randomly allocated through an independent remote telephone service managed by the Manchester Academic Health Sciences Centre Trials Coordination Unit, stratified by centre, with a block size of 18. The therapy for the intervention group consisted of groups of nine patients. After recruiting each set of 18 women at each centre, participants were block randomised into the two groups, resulting in nine women in the intervention group and nine in the control group.

Efforts were made to ensure that the period between consent and randomisation did not exceed 4 weeks. General practitioners (GPs) were notified of their patient's participation in the trial. It was not possible to mask the participating mothers, their GPs, or practice health visitors to the treatment group.

Procedures

The PHP is a structured intervention consisting of 12 group-based sessions, combining CBT-based strategies with culturally relevant adaptations for British south Asian women with postnatal depression.[19,20,24] Initially, sessions were held weekly for 2 months, then every 2 weeks for an additional 2 months, with each session lasting 60–90 min. The sessions were delivered in languages preferred by the trial participants; following randomisation, the individuals were contacted to understand language preference and any other barriers to participation, and this would determine the allocation of facilitators, such that at least one facilitator was usually allocated who spoke the most common language reported by the participants. The PHP

educated participants about depression and addressed nine culturally specific topics, including the challenges of being a British south Asian woman, the role of religion and spirituality in mental health, issues affecting self-esteem and their management, exercise, relaxation, assertiveness, self-confidence, and tackling social isolation, all aimed at raising awareness and improving wellbeing. The PHP was delivered by non-specialist workers, who were trained NHS band 4–7 researchers, with backgrounds in psychology, social sciences, or related fields, but no experience in delivering CBT. Details about the intervention content, training, and supervision procedures for non-specialist workers are summarised in the appendix (pp 1–2) and can be found in the protocol.[23] The training of non-specialist workers for intervention delivery focused on mastery of facilitation, behavioural activation, and the ABC model of CBT. It involved a didactic and Socratic teaching approach, with verbalisation of the contents of the intervention via presentations, role-plays, and dialogue in discussions. PHP trainers observed facilitators for at least one session, provided practical feedback, and suggested improvement where required.

See Online for appendix

Treatment as usual for the control group involved routine mental health assessments, care by the GP, routine management and monitoring of the condition, referral to talking therapies, and antidepressant medications as needed. More details about the use of health services are provided in the appendix (pp 3–5).

Following the introduction of physical distancing measures in the UK during the COVID-19 pandemic, the team swiftly implemented a continuity plan to ensure delivery to time and target could be maintained with regard to all governance and operational aspects. At a time of particular vulnerability for an already disadvantaged group, the research team, in coordination with the participants and experts on participant and public involvement and engagement, ensured measures could be put in place that allowed contact to be maintained in line with the study protocol.

On March 23, 2020, Public Health England (PHE) guidance was issued and lockdown procedures were implemented across all sites, and it was not possible to deliver the above without some changes. We held remote 1:1 discussions with the study participants to understand their views and suggestions for possible solutions, and the consensus was they did not want the study to be paused or for intervention delivery to not go ahead as planned.

To comply with PHE guidance and follow physical distancing guidelines, the PHP intervention was delivered remotely via Zoom, Microsoft Teams, or Google Meet, rather than in in-person groups. Updated ethical approvals, guidance, and delivery materials to facilitate the change in format were developed, together with comprehensive training of research team members under supervision of senior investigators.

Assessments were done at baseline (ie, randomisation), immediately post-intervention (around 4 months from randomisation), and at 12 months from randomisation and were conducted at participants' homes or other preferred locations, and in the participant's preferred language, including Urdu, Bengali, Gujarati, Punjabi, Hindi, and Tamil. Research assistants administered all questionnaires at baseline, post-intervention (4 months), and 12 months, except for the SCID-5 which was administered only at baseline. Assessments included the Hamilton Depression Rating Scale (HDRS) to assess the severity of depression, with higher scores indicating higher severity and scores of 7 or lower considered to indicate remission;[25] the PHQ-9, a self-report measure of depression scored from 0–27 (categorised as minimal depression [score 0–9], minor depression [10–14], major depression [15–19]; and severe depression [20–27]);[26] the seven-item Generalized Anxiety Disorder (GAD-7) scale (with scores categorised as minimal anxiety [0–4], mild anxiety [5–9], moderate anxiety [10–14], and severe anxiety [≥15]);[27] social functioning score,[28,29] a self-report measure of daily functioning based on ten items, with questions scored on a 5-point Likert scale from 0 (no difficulty) to 4 (often cannot do the task) and overall scores ranging from 0 to 40, where higher scores indicate higher social dysfunction; the EuroQol EQ-5D-3L scale to evaluate quality of life and health status across five dimensions (mobility, self-care, usual activity, pain or discomfort, and anxiety or depression) for which participants rated themselves as having no, some, or extreme problems, in addition to giving a 0–100 rating of their overall health state on a visual analogue scale (VAS), where higher scores indicated a better health state;[30,31] and the Parenting Sense of Competence Scale (PSCS) to measure perceived parenting competence across 16 items (nine on satisfaction and seven on efficacy), scored on a 6-point Likert scale from 1 (strongly disagree) to 6 (strongly agree), with overall scores ranging from 16 to 96 and higher scores indicating a higher sense of competence.[32] All measures were available in Urdu, Hindi, Bengali, Gujarati, and Tamil languages. The IAPT Patient Experience Questionnaire was also used to record individuals' experiences of the intervention at the 4-month and 12-month follow-ups; patients self-reported their level of satisfaction from not at all satisfied to completely satisfied. The trial protocol provides details about the outcome assessments used in the trial.[23]

Outcomes

The primary outcome measure was remission or recovery from depression post-intervention, defined by a HDRS score of 7 or lower at 4 months.[25] Treatment response was also assessed as a prespecified secondary outcome, defined as a reduction of at least 50% in depressive symptom severity as measured by the HDRS across the three timepoints (baseline, post-intervention, and 12 months). Other prespecified secondary outcomes included depressive symptom severity on the PHQ-9, anxiety symptom severity on the GAD-7, and psychosocial health indicators: social functioning, quality of life (EQ-5D-3L score), and parenting competence (PSCS score). Two prespecified

outcomes pertaining to cost-effectiveness and child outcomes will be reported elsewhere.

Statistical analysis

Previous studies on psychological treatments for postnatal depression indicate that a 20 percentage points decrease in the proportion of trial participants meeting the criteria for depression on the HDRS is clinically meaningful.[33] As such, we sought 90% power to identify a more conservative 15 percentage points difference between a 55% recovery rate in the intervention group and a 40% recovery rate in the control group. Assuming an intraclass correlation of 0·05 for group treatment,[33] a 75% follow-up rate at 4 months, a 70% follow-up rate at 12 months, and a 5% significance level, we estimated that the target sample size was 720 participants, with 360 in the intervention group (consisting of 40 groups of nine participants each) and 360 in the control group.

All statistical analyses were done according to a predefined statistical analysis plan (appendix p 2). Intervention effects were analysed on an intention-to-treat basis. For the primary efficacy endpoint (odds of recovery from postnatal depression at 4 months), we fitted a random-effects logistic regression model to account for the longitudinal nature of the data, including fixed covariates for study site, baseline depression severity (HDRS score), parity, and years in education. Based on the work by Roberts and Roberts,[34] random intercepts were also included for each individual (ie, clusters of size 1) in the control group. Similar logistic random-effects models were also implemented for secondary outcomes, including odds of recovery from postnatal depression at 12 months and treatment response on HDRS at 4 months and 12 months. For continuous secondary outcomes, we used a linear random-effects model with the aforementioned covariates plus the baseline measure of the outcome. For all analyses, two-sided $p<0·05$ was considered statistically significant.

For psychometric measures, when data were missing for fewer than half of the questions, the mean value was imputed. Following this, there remained a high proportion of patients with missing data for the primary outcome. Logistic regression models were used to investigate whether baseline covariates predicted missingness, and showed little evidence of a departure from being missing completely at random (see appendix p 2 for further details on this analysis). Therefore, all the main analyses were conducted on those with non-missing outcome data. We also did a sensitivity analysis in which all participants with a missing primary outcome were assumed to have not recovered and were coded as having depression.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

9136 individuals were approached for recruitment between Feb 8, 2017, and March 29, 2020 (with the final participant consenting on Dec 16, 2019). 6176 (68%) of these individuals were eligible for screening, of whom 4296 (70%) gave informed consent and completed the PHQ-9. 1064 (25%) of those assessed scored 10 or higher on the PHQ-9 and were eligible for the second stage assessment with the SCID-5. 741 (70%) of 1064 participants scored positively on the SCID-5, of whom 732 (99%) continued consent for participation and were randomly allocated: 368 to the PHP group and 364 to the control group (figure 1). 283 participants in each group had at least one response on the HDRS at 4 months.

All randomly allocated participants were included in the intention-to-treat analysis. Of the 368 participants in the treatment group, 246 (67%) were considered compliant with the treatment (attending at least one session). A breakdown of participants' adherence to the sessions is provided in the appendix (p 9). Baseline demographic data are presented in table 1. Participants were mostly of Pakistani (397 [55%] of 719 with available data), Indian (176 [24%]), or Bangladeshi ethnicity (127 [18%]), with an overall mean age of 31·4 years (SD 5·2), with their youngest infants having a mean age of 23·6 weeks (14·2).

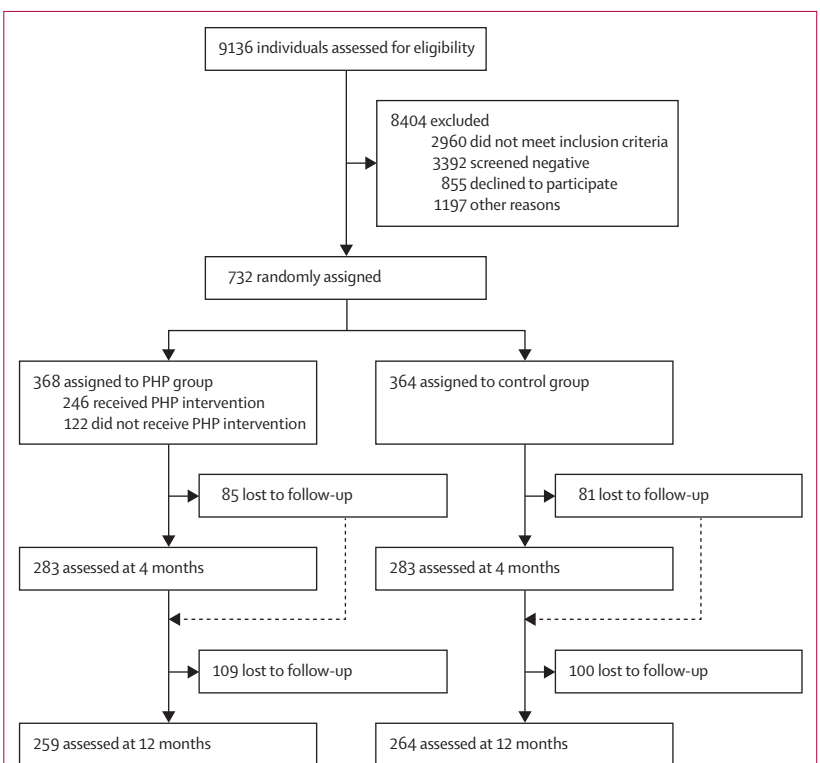

Figure 1: **Trial profile**
Numbers shown as assessed at 4 months and 12 months are those who had at least one response on the Hamilton Depression Rating Scale at that timepoint; however, the analyses included only participants with responses to at least half of the questions (see table 2 for numbers). PHP=Positive Health Programme.

	Positive Health Programme group (N=368)	Control group (N=364)
Age, years	31·3 (5·2), N=364	31·4 (5·2), N=355
Years in education	13·9 (3·6), N=300	13·7 (4·0), N=301
Years married (if married)	6·7 (4·8), N=345	7·0 (5·0), N=326
Age of youngest child, weeks	23·7 (14·1), N=307	23·6 (14·3), N=306
Number of people living in household	5·0 (1·9), N=359	5·2 (2·1), N=351
Hamilton Depression Rating Scale score	17·6 (7·3), N=367	18·0 (7·3), N=361
Ethnicity		
Indian	91/365 (25%)	85/354 (24%)
Bangladeshi	60/365 (16%)	67/354 (19%)
Pakistani	202/365 (55%)	195/354 (55%)
Other south Asian	12/365 (3%)	7/354 (2%)
English speaking		
Yes	338/363 (93%)	327/352 (93%)
No	25/363 (7%)	25/352 (7%)
Religion		
Islam	322/366 (88%)	315/357 (88%)
Hinduism	23/366 (6%)	28/357 (8%)
Christianity	2/366 (1%)	4/357 (1%)
Buddhism	3/366 (1%)	0/357
Sikhism	16/366 (4%)	9/357 (3%)
Other	0/366	1/357 (<1%)
Generational status*		
First generation	206/364 (57%)	215/353 (61%)
Second generation	120/364 (33%)	103/353 (29%)
Third generation	38/364 (10%)	35/353 (10%)
Employment status		
Full-time	42/365 (12%)	44/352 (13%)
Part-time	56/365 (15%)	43/352 (12%)
Unemployed	39/365 (11%)	43/352 (12%)
Sick	1/365 (<1%)	0/352
Housewife	197/365 (54%)	186/352 (53%)
Student	2/365 (1%)	3/352 (1%)
Other	28/365 (8%)	33/352 (9%)
Nature of employment at time of assessment		
Current employment	97/364 (27%)	93/349 (27%)
Previous employment	2/364 (1%)	2/349 (1%)
Partner employed	1/364 (<1%)	4/349 (1%)
Not applicable	264/364 (73%)	250/349 (72%)

(Table 1 continues in next column)

(Continued from previous column)

	Positive Health Programme group (N=368)	Control group (N=364)
Highest educational qualification		
Primary	12/352 (3%)	14/349 (4%)
GCSE	49/352 (14%)	68/349 (19%)
A-level	80/352 (23%)	70/349 (20%)
Undergraduate degree	121/352 (34%)	100/349 (29%)
Postgraduate degree	60/352 (17%)	59/349 (17%)
Other	30/352 (9%)	38/349 (11%)
Marital status		
Single	4/366 (1%)	7/356 (2%)
Married or cohabiting	349/366 (95%)	335/356 (94%)
Divorced or separated	13/366 (4%)	14/356 (4%)
Previously separated or widowed		
Divorced	31/330 (9%)	30/318 (9%)
Separated	15/330 (5%)	14/318 (4%)
Widowed	1/330 (<1%)	5/318 (2%)
Not applicable	283/330 (86%)	269/318 (85%)
Number of male children		
0	93/357 (26%)	103/344 (30%)
1	166/357 (46%)	158/344 (46%)
2	72/357 (20%)	64/344 (19%)
3	22/357 (6%)	14/344 (4%)
≥4	4/357 (1%)	5/344 (1%)
Number of female children		
0	107/350 (31%)	88/336 (26%)
1	143/350 (41%)	142/336 (42%)
2	70/350 (20%)	76/336 (23%)
3	25/350 (7%)	24/336 (7%)
≥4	5/350 (1%)	6/336 (2%)
Living with extended family		
Yes	111/363 (31%)	109/352 (31%)
No	252/363 (69%)	243/352 (69%)

Data are mean (SD) or n/N (%). GCSE=General Certificate of Secondary Education. A-level=General Certificate of Education Advanced Level. *Generations since a family's migration from south Asia to the UK, where "first generation" refers to those who immigrated to the UK during their lifetime, "second generation" to their children, and "third generation" to their grandchildren.

Table 1: **Baseline characteristics of study participants**

The completeness of study outcome measures (ie, participants with at least half of the questions answered on a given scale) at the three assessment timepoints of the study (baseline, 4 months, and 12 months follow-up) is indicated in table 2.

Clinical outcomes at different timepoints are presented in table 2. In terms of the primary outcome of recovery from depression (HDRS score ≤7) at 4 months, 138 (49%) of 281 in the PHP group recovered, compared with 105 (37%) of 281 in the control group (figure 2). Adjusting for baseline covariates, participants in the PHP group were estimated to be almost twice as likely to have recovered at 4 months than those in the control group (adjusted odds ratio [aOR] 1·97 [95% CI 1·26–3·10]).

By 12 months, 141 (54%) of 259 in the PHP group and 140 (54%) of 261 in the control group showed recovery from depression on the HDRS, with no significant difference between groups (aOR 1·02 [95% CI 0·62–1·66]; table 2; figure 2). Absolute values for primary and secondary outcomes pertaining to depressive and anxiety symptom measures at the three timepoints are presented in the appendix (p 7).

	Positive Health Programme group		Control group		Adjusted OR* or difference† (95% CI)	p value
	N	n (%) or mean (SD)	N	n (%) or mean (SD)		
Primary outcome						
Recovery from depression (HDRS score ≤7)						
4 months						
Yes	281	138 (49%)	281	105 (37%)	1·97 (1·26 to 3·10)	0·0030
No	281	143 (51%)	281	176 (63%)	1 (ref)	..
12 months						
Yes	259	141 (54%)	261	140 (54%)	1·02 (0·62 to 1·66)	0·80
No	259	118 (46%)	261	121 (46%)	1 (ref)	..
Secondary outcomes						
Treatment response on HDRS‡						
4 months						
Yes	281	158 (56%)	279	112 (40%)	2·49 (1·38 to 4·52)	0·0026
No	281	123 (44%)	279	167 (60%)	1 (ref)	..
12 months						
Yes	259	158 (61%)	260	151 (58%)	1·07 (0·59 to 1·95)	0·82
No	259	101 (39%)	260	109 (42%)	1 (ref)	..
PHQ-9 score						
Baseline	368	15·21 (3·93)	361	15·85 (4·21)	..	..
4 months	282	7·22 (5·80)	280	9·09 (6·34)	−2·05 (−3·18 to −0·92)	<0·0001
12 months	258	6·77 (5·55)	260	7·60 (6·81)	−0·89 (−2·05 to 0·27)	0·13
GAD-7 score						
Baseline	364	11·56 (5·87)	356	11·60 (5·62)	..	..
4 months	279	6·05 (5·66)	277	7·37 (5·71)	−1·45 (−2·66 to −0·25)	0·018
12 months	256	5·95 (5·51)	259	6·40 (6·26)	−0·24 (−1·46 to 0·99)	0·71
PSCS score						
Baseline	337	63·00 (12·01)	321	62·36 (10·92)	..	..
4 months	252	69·13 (12·25)	247	67·19 (10·77)	1·76 (−0·37 to 3·89)	0·11
12 months	226	69·88 (12·32)	225	67·43 (12·61)	3·32 (1·10 to 5·54)	0·0034
Social functioning score						
Baseline	352	12·91 (9·85)	337	12·98 (9·67)	..	..
4 months	262	6·62 (7·76)	267	8·04 (8·75)	−1·57 (−3·74 to 0·59)	0·16
12 months	246	6·05 (7·98)	250	6·73 (8·77)	−0·34 (−2·51 to 1·83)	0·76
EQ-5D-3L VAS score						
Baseline	354	55·43 (19·80)	342	55·28 (20·44)	..	..
4 months	271	66·20 (21·60)	268	64·26 (21·55)	3·30 (−0·35 to 6·95)	0·077
12 months	256	68·12 (21·10)	257	65·93 (21·71)	3·48 (−0·28 to 7·23)	0·069
Satisfaction with treatment						
4 months						
Yes	260	242 (93%)	257	222 (86%)	2·72 (1·05 to 7·09)	0·040
No	260	18 (7%)	257	35 (14%)	1 (ref)	..
12 months						
Yes	252	235 (93%)	248	224 (90%)	2·03 (0·77 to 5·40)	0·16
No	252	17 (7%)	248	24 (10%)	1 (ref)	..

N values show the number of participants who answered at least half of the questions for the given scale and were included in the analysis. Binary outcomes (recovery, treatment response, and satisfaction with assessment) are presented as n (%) per group, with adjusted ORs (95% CI) for between-group comparisons. All other outcomes are presented as mean score (SD) per group, with adjusted differences (95% CI) for between-group comparisons. HDRS=Hamilton Depression Rating Scale. OR=odds ratio. PHQ-9=nine-item Patient Health Questionnaire. GAD-7=seven-item Generalized Anxiety Disorder. PSCS=Parenting Sense of Competence Scale. VAS=visual analogue scale. *Adjusted for therapist (random effect), baseline HDRS score, parity, and years in education. †Adjusted for therapist (random effect), baseline HDRS score, parity, education, and baseline value of outcome variable. ‡Defined as a ≥50% reduction in HDRS score compared with baseline.

Table 2: **Summary statistics by follow-up timepoint and adjusted effect sizes for primary and secondary outcomes**

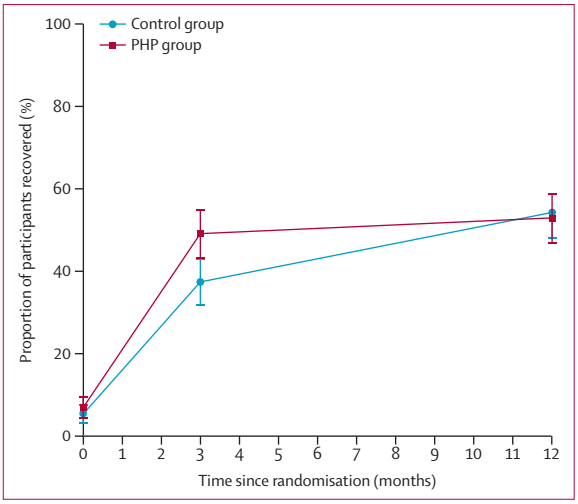

Figure 2: **Recovery from postnatal depression (primary outcome)**
Proportions of patients who had recovered from depression (defined as a score of ≤7 on the Hamilton Depression Rating Scale) at the three assessment timepoints. PHP=Positive Health Programme.

At 4 months, treatment responses (defined as ≥50% reduction in HDRS score from baseline) were observed in 158 (56%) of 281 participants in the PHP group and 112 (40%) of 279 participants in the control group (aOR 2·49 [95% CI 1·38–4·52]). At 12 months, 158 (61%) of 259 participants in the PHP group and 151 (58%) of 260 in the control group had a treatment response on the HDRS, with no statistically significant difference between groups (table 2).

Significantly lower depression scores on the PHQ-9 were recorded in the PHP group than in the control group at 4 months (adjusted difference –2·05 [95% CI –3·18 to –0·92]; table 2). In the PHP group, the frequency of participants with major depression or severe major depression (defined as a PHQ-9 score ≥15) reduced from 184 (50%) of 368 at baseline to 39 (14%) of 282 at 4 months and 31 (12%) of 258 at 12 months. By comparison, the frequency of control group participants with major depression or severe major depression reduced from 211 (58%) of 361 at baseline to 58 (21%) of 280 at 4 months and 54 (21%) of 260 at 12 months (appendix p 7). The PHP group also had significantly lower GAD-7 scores (indicating reduced anxiety) compared with the control group (adjusted difference –1·45 [–2·66 to –0·25]). No statistically significant effects of the intervention on the reduction of anxiety and depressive symptoms were observed at 12 months (table 2).

Regarding parenting competence outcomes, there was no significant difference in PSCS scores at 4 months between the PHP and control groups. However, at 12 months, the PHP group had a significantly higher mean score (adjusted difference 3·32 points [95% CI 1·10–5·54]), indicating a higher sense of competence in parenting compared with the control group. There were no significant differences in EQ-5D-3L VAS scores, measuring the patient's health state on the day of assessment, between the groups at any timepoint (table 2). At 4 months, based on the IAPT Patient Experience Questionnaire, the PHP group was significantly more likely to be satisfied with the treatment offered than the control group (aOR 2·72 [95% CI 1·05–7·09]), while social functioning score did not differ significantly between groups. At 12 months, there was no significant difference in satisfaction or social functioning score between groups (table 2).

At 4 months, 170 (23%) of 720 participants had missing data for the primary outcome of recovery from postnatal depression, with approximately equal distribution between the two study groups (data missing for 87 [24%] of 368 participants in the PHP group and 83 [23%] of 364 in the control group). The sensitivity analysis found that at 4 months, those in the PHP group were more likely to have recovered from postnatal depression than those in the control group, even when assuming that all those with missing outcomes had depression (aOR 1·63 [95% CI 1·08–2·46]; appendix p 8). At 12 months, there was no significant difference between the two groups in the proportions of patients who were recovered in this sensitivity analysis (0·97 [0·65–1·43]).

Discussion

This trial presents evidence of the clinical efficacy of a group-based CBT intervention, the PHP, delivered by non-specialist workers among south Asian women in the UK. Compared with treatment as usual, we observed a higher proportion of participants recovering from postnatal depression 4 months after the start of the PHP intervention, as measured on the HDRS. At 12 months (ie, around 8 months after the intervention ended), the proportion of participants who had recovered did not significantly differ between the two groups. Similar trends were observed in the severity of anxiety and depressive symptoms based on the GAD-7 and PHQ-9, respectively, as well as in treatment satisfaction. The PHP programme showed significant improvement over treatment as usual in the participants' sense of parenting competence at 12 months, but not at 4 months. Our findings suggest that the PHP intervention could considerably reduce the duration of a depressive episode as compared with treatment as usual in the postnatal period, a crucial time when maternal depression is likely to impact various infant outcomes. These findings are therefore important from a public health perspective.

The ROSHNI-2 trial addresses the existing treatment gap in postnatal depression by establishing that non-specialist workers can successfully engage and deliver CBT to underserved minority ethnic groups. There is evidence from the global literature on the benefits of involving non-specialist workers in mental health care,[9,35,36] but studies examining non-specialist worker-delivered CBT for minority ethnic groups in

high-income countries are few in number. A cluster-randomised controlled trial by Morrell and colleagues in the UK showed the efficacy of non-specialist worker-delivered CBT and counselling-based interventions;[37] trained health visitors were proficient in identifying women with postnatal depression and providing effective cognitive-behavioural or counselling-based approaches.[37] A systematic review, focusing primarily on studies from low-income and middle-income countries, also supports the effectiveness of group CBT for postnatal depression, showing moderate to large treatment effect sizes.[36]

The scarcity of research on the effectiveness of psychological interventions for minority ethnic groups might be a reflection of the barriers faced by these groups in accessing such care. Our preliminary work with south Asian women in the UK uncovered several such barriers to care,[19,20,24] including a scarcity of culturally informed care and the huge stigma against mental disorder in south Asian communities. Psychological interventions that do not address these key barriers are unlikely to be accessible to south Asian minority ethnic groups.[19,20,24] The ROSHNI-2 trial supports the observations from our formative work, showing that culturally sensitive approaches are successful in engaging minority ethnic groups with research and interventions, and that such interventions are clinically effective.

Although there was no significant difference in improvement compared with the control group at the 12-month assessment, the earlier recovery in the intervention group is important. This is primarily because postnatal depression affects optimal childcare and is associated with poor child development outcomes.[2,5,6,36] The intervention further showed a sustained, positive effect on crucial areas such as perceived parental childcare competency. These improvements are important as they help to mitigate the potential intergenerational effects associated with postnatal depression.[6,35] Furthermore, participants who received the intervention reported higher satisfaction with their treatment than those receiving treatment as usual.

The faster recovery from postnatal depression for participants in the PHP group holds considerable value for the participants themselves and potentially for their infants and other family members. It is notable that a substantial proportion of cases of depression are characterised by a prolonged history of depressive symptoms and poor outcomes, exhibiting either fluctuating or sustained patterns.[35,38,39] A more timely and rapid recovery from depression could help alleviate its chronic progression patterns.[35,38,39] Besides this observation, the focus of intervention for postnatal depression should extend beyond the commonplace short-term efficacy outcomes in treatment evaluation research, towards enhancing the quality of life, social functioning, and mother–infant relationship.[40–42]

Although this trial presents evidence for an accessible and acceptable intervention that generates real benefits for an underserved group, future research is needed to develop strategies for maintaining sustained benefits in a scalable way. Potential strategies could concentrate on maintaining contact to further extend the treatment effects, and testing whether providing such extended treatment is helpful and what frequency is optimal. The prioritisation of intervention development and long-term outcome evaluation should be embraced, mirroring standard practice in the evaluation of complex interventions.[43] Currently, we are exploring a remote PHP intervention, which could offer a cost-effective solution for ensuring a long-term impact.

Our findings are supported by trials of similar interventions tested among postnatal women in south Asia, including two major trials[33,44] of the Thinking Healthy Programme delivered by community health workers in Pakistan and by peers (local lay women with a similar sociodemographic profile to the target mothers) in both Pakistan and India. In a cluster-randomised trial, Rahman and colleagues found that 16 sessions of the Thinking Healthy Programme delivered by community health workers yielded strong effect sizes for reduced postnatal depression at 6 months (aOR 0·22 [95% CI 0·14–0·36]) and sustained remission of postnatal depression at 12 months (0·23 [0·15–0·36]).[33] Small improvements were also observed when this intervention was delivered by peers in India, where 89 (73%) of 122 women in the intervention group attained remission, compared with 77 (60%) 129 in the control group.[44] This intervention was also found to be relatively cost-effective by reducing health-care costs, time costs, and productivity costs.[33,44] WHO has endorsed these interventions for preventing and treating postnatal depression in recent guidelines.[9–11] Additionally, in Pakistan, the Learning Through Play Plus programme, an integrated intervention that combines the Thinking Healthy Programme approach with child psychostimulation, has shown statistically significant improvements in maternal depression, enhanced maternal and child functioning, and better child health outcomes.[45,46]

The strengths of the ROSHNI-2 trial were its robust design, large sample size, and participation of multiple UK trial sites, reflecting a diverse population for better generalisability. The application of clinical interviews for diagnosis, and rater-blind standardised assessments of outcomes, further bolster the study's validity. Moreover, considerable efforts were invested in formative research to ensure that the intervention was culturally informed. Our investigator team included global experts with extensive experience of developing interventions in the south Asian context. The lessons learned from this formative and consultative work, including participatory approaches, cultural adaptation of CBT, and strategies for engagement (panel), offer generalisable insights applicable to south Asian populations in the UK.[19,20,23,24]

These insights could serve to diversify research participation in future studies.

The ROSHNI-2 trial is one of the largest trials to date conducted to evaluate a psychological intervention for underserved populations. It marks a considerable advancement in trial methodology, generating knowledge of how to increase engagement with research and address stigma in underserved groups where such engagement can be challenging, which is a priority for the UK Department of Health and Social Care.[18,47–49] The development of the PHP intervention was centred around co-production with service user groups, leading to a high rate of recruitment and retention. Considering that minority ethnic groups were particularly susceptible to poor COVID-19 outcomes and a higher risk of postnatal depression during the COVID-19 pandemic,[13] the study adapted by shifting from in-person to remote delivery, thereby maintaining the continuity of intervention sessions online and minimising dropouts. Moreover, 67% of those in the PHP group adhered to the intervention by attending at least one session.

Efforts made to facilitate recruitment and engagement with research (panel)[24] included strategies for adapting recruitment, screening, and assessment procedures. This work can provide valuable insights for research studies, especially those emphasising inclusivity and enhanced access for socioeconomically disadvantaged groups. While this model was initially implemented with British south Asian women, some of the methods used for community engagement are applicable to other minority ethnic groups globally and other socioeconomically disadvantaged populations in the UK. These strategies can be beneficial beyond the research setting, potentially improving service pathways and facilitating greater access.

The study has several limitations. It was not possible to mask the study participants to treatment allocation due to the nature of the intervention. However, outcome assessments were done by independent team members not involved in intervention delivery or group allocation. Recruitment across sites was not uniform, with one study site (Glasgow) having relatively low recruitment due to its smaller south Asian population and a lower birth rate. Another shortcoming is that the study's findings, based solely on a cohort of British south Asian women, might not be generalisable to other minority ethnic groups elsewhere in the world. However, the results were informed by and in line with other international studies globally.[36] Furthermore, the geographical closeness of many participants could imply potential acquaintance, and the sharing of intervention experiences could inadvertently introduce a contamination bias.

Our study had a relatively high proportion of missing data. However, the consistency of findings between our primary and sensitivity analyses is encouraging.

For sample size calculation, we identified a 20 percentage point difference as clinically meaningful based on previous literature, particularly the Thinking Healthy Programme,[33] with a conservative estimate set at 15 percentage points. However, the primary outcome revealed a difference of 12 percentage points, with recovery in 49% of patients in the PHP group compared with 37% in the control group at 4 months. While this observed effect size is smaller than our conservative estimate, it remains statistically significant and clinically relevant. Several factors could have contributed to this variance. The heterogeneity within our study population, including variability in baseline characteristics such as symptom severity and comorbid conditions, could have influenced individual responses to the intervention. Furthermore, despite our efforts to maintain high fidelity in the delivery of both PHP and treatment as usual, electronic delivery of the intervention during the COVID-19 pandemic period might have attenuated the expected effect. These limitations suggest the need for further refinement in future studies to optimise the effectiveness of the interventions.

The scalability of our approaches to bolster engagement with research and services might be a challenge within a budget-constrained, publicly funded service. Providing childcare facilities or reimbursing travel expenses for group participants might not be financially viable at scale. Further research is also needed to compare online versus face-to-face delivery of interventions, as the former are likely to be cost-effective. However, virtual delivery requires some familiarity with technology and could increase inequalities due to the digital divide.

While our study aimed to demonstrate the feasibility and benefits of engaging British south Asian women in culturally adapted CBT to reduce postnatal depression, it is important to recognise several other social determinants contributing to postnatal depression that cannot be addressed by our intervention. Some studies show that domestic violence and abuse is prevalent in this community, as in many others, and has major implications for the health of mothers, babies, and families.[50,51] Within the PHP interviews used to develop the intervention, the presence of domestic violence and abuse was evident, often referred to as "marital disharmony", and was identified by women as a major cause of their depression. Further research is necessary on the incorporation of strategies to tackle domestic violence and abuse into multicomponent preventive and treatment interventions for postnatal depression.

Future research should also focus on the integration and implementation of the PHP within existing health-care frameworks, particularly the NHS Talking Therapies service and third-sector services. Conducting theory-of-change studies will be crucial in identifying the necessary steps and resources required to adapt and scale the PHP intervention effectively within these structures.[52] Additionally, using the concepts of implementation science, we propose designing implementation-focused trials that address crucial aspects for successful deployment.[53] These trials should assess the reach of the

intervention to ensure it effectively targets the intended population, measure its impact on desired outcomes (effectiveness and efficacy), and evaluate its acceptance and uptake by staff, settings, systems, and communities (adoption). Furthermore, monitoring the consistency of delivery, associated costs, and any adaptations made during implementation will be essential. Finally, investigating the long-term maintenance and sustainability of the intervention effects in individuals and settings over time will provide comprehensive insights. These implementation-focused trials could offer valuable information on the practical aspects of deploying the PHP model, ensuring its effective and sustainable integration into existing health-care and community support systems.

This study has several policy implications. Therapeutic approaches such as CBT and interpersonal therapy have been shown to be effective for managing postnatal depression and are recommended as first-line treatments in NICE guidance.[17] Nevertheless, there is a well established ethnic disparity in the research and provision of and access to postnatal depression services in the UK, particularly in British south Asian women. These women frequently live in economically disadvantaged areas and, due to numerous psychosocial issues, language barriers, and cultural obstacles, are often deemed easy to ignore and difficult to engage. This situation constitutes a substantial public health issue given that this demographic group represents the largest minority ethnic group in the UK and has one of the highest birth rates in the country.[54]

An important consideration when comparing these results with previous studies is the scarcity of research involving women of minority ethnic backgrounds, which limits direct comparisons. The heightened birth rates and increased disparities, particularly underscored during the COVID-19 pandemic, emphasise the need for culturally appropriate interventions that cater to the specific needs of this community. The PHP could be an effective addition to publicly funded talking therapies for treating depression and anxiety in women of south Asian minority groups and other populations. The ROSHNI-2 team's adeptness in recruiting participants, transitioning the PHP from in-person to remote delivery, and retaining participants reflects a deep understanding of and ability to navigate the complexities of cultural engagement, a skill honed during the ROSHNI-2 project. These outcomes suggest the potential for developing and testing models of care aimed at addressing treatment effectiveness of remote interventions. Future research should prioritise strategies to expand the PHP, incorporating similar interventions into public mental health-care frameworks, with the aim of long-term benefits.

Contributors

All listed authors have been with the project team from the initial bid submission for funding to the development of the protocol. FL, NH, AW, and DS drafted the paper, and all other authors critiqued the output for important intellectual content. NH is the study chief investigator with overall responsibility for the study and the decision to submit for publication. FL was part of the exploratory phase of this trial and contributed to the submission of the bid, delivery and management of the project, and stakeholder and patient and public engagement and dissemination. SA is the qualitative researcher on the project alongside JMi and DS. WW supported in the development of culturally adapted recruitment methodology and training of researchers in recruitment to this study population. NM supported the team in community engagement, tackling stigma, and promoting family involvement by sharing his lived experiences and the development of outputs from this work. NZ contributed to the data management plan and statistical analysis plan and management of all data from the project. CAC-G and PBe are the qualitative research methods leads. RE is the study trial statistician and the study statistical analysis and write-up was supported by MP and AW. KL is the lead for supervision of the intervention training and delivery. RM is the site lead for the Midlands supported by TB and JK. IM and KB are the site leads for the London site. CW and JMo are site leads for the Glasgow site. NS is the site lead for Yorkshire. AU and LD were responsible for the health economics component of the project including analysis and write-up. RE, MP, and AW accessed and verified data as part of analysis. FL and NZ accessed and verified data as per the data management, data cleaning, and preparation for data analysis steps of the trial. AR contributed in an advisory capacity to conceptualisation, design, and running of the study. All authors had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Declaration of interests

CW has written two CBT-based self-help resources for postnatal low mood and class-based and online postnatal low mood courses unrelated to the PHP; and is the Director of Five Areas, a limited company that commercialises these resources and of which he is a shareholder. NH has been a past Trustee of the Pakistan Institute of Living and Learning, Abaseen Foundation UK, Lancashire Mind UK, and Manchester Global Foundation; is an executive member of the Academic Faculty at the Royal College of Psychiatrists, London; and is an NIHR Senior Investigator. All other authors declare no competing interests.

Data sharing

Reasonable requests for patient-level data should be made to the corresponding author and will be considered by the ROSHNI-2 trial management group. The ROSHNI-2 management team and sponsor will consider the sharing of data on a case-by-case basis in line with the ethics approval and patient information sheets. Any presented data do not contain any direct identifiers.

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Extended Research Article

A group psychological intervention for postnatal depression in British mothers of South Asian origin – the ROSHNI-2 RCT

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This article

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Abstract

Background: Postnatal depression is more common in British South Asian women than white women in the United Kingdom. Despite empirical evidence suggesting the effectiveness of cognitive–behavioural therapy as a first line of treatment, little evidence is available regarding its applicability to different minority ethnic groups.

Objectives: Determining the clinical and cost-effectiveness of a culturally adapted group psychological intervention (Positive Health Programme) in primary care for British South Asian women with postnatal depression compared with treatment as usual.

Setting: General practices and children's centres in the North West, East Midlands, Yorkshire, Glasgow and London.

Participants: British South Asian women meeting the *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) depression criteria, aged 16 years or above, with infants up to 12 months.

Design: A multicentre randomised controlled trial with an internal pilot and partially nested design to compare treatment as usual plus the Positive Health Programme with treatment as usual in British South Asian women with postnatal depression, with a qualitative study to examine the acceptability and feasibility of the intervention.

Intervention: The Positive Health Programme, a culturally adapted group intervention based on the principles of cognitive–behavioural therapy delivered by facilitators over 12 sessions.

Outcomes measures: The primary outcome was recovery from depression (Hamilton Depression Rating Scale ≤ 7) at end of intervention (approximately 4–6 months). Analysis of the primary outcome and the long-term follow-up (at 12 months) used a logistic random-effects model to estimate the odds ratio of caseness between treatments, adjusting for centre, severity of depression and education at baseline. Cost data were collected using an Economic Patient Questionnaire.

Results: Seven hundred and thirty-two participants across four study centres were randomised by the Manchester Clinical Trials Unit. At 4 months, almost half of patients in the treatment (Positive Health Programme) group were recovered (138 or 49%), whereas 105 (37%) were recovered in the control (treatment as usual) group. By 12 months, the control (treatment as usual) and treatment (Positive Health Programme) group had over 50% recovery at 140 (54%) and 141 (54%), respectively. For the primary outcome, recovery from postnatal depression at end of intervention, we found a significant effect such that the odds of achieving recovery in the treatment group were almost twice as high compared to the treatment as usual group (odds ratio 1.97, 95% confidence interval 1.26 to 3.10). Between the two groups, there was no significant difference in the odds of recovery at 12 months (odds ratio 1.02, 95% confidence interval 0.62 to 1.66), highlighting a need for more intensive therapies and/or longer-term care plans for this group of patients.

Qualitative results: The intervention was considered feasible and acceptable from the perspectives of Positive Health Programme participants, facilitators, and general practitioners. The findings suggest improved emotional and social support and an enhanced sense of well-being.

Economic evaluation: Positive Health Programme implementation was estimated to cost an average of £408 per participant. The intention-to-treat analysis shows that the Positive Health Programme intervention costs £22,198 per quality-adjusted life-year gain. Positive Health Programme was cost-effective on average but with a substantial uncertainty: the probability that Positive Health Programme was cost-effective was 44% (65%) at the willingness to pay £20,000 (£30,000) per quality-adjusted life-year. The Positive Health Programme was highly cost-effective for those who attended 5–8 sessions, costing £9040 per quality-adjusted life-year.

Limitations: The study sample limits generalisability with other ethnic minority groups, and the cost-effectiveness analysis did not explore recall bias.

Conclusions: The results of this study provide robust evidence that the culturally adapted psychological intervention for postnatal depression in South Asian women is effective at the primary end point and acceptable to women.

Future work: Further development of the Positive Health Programme intervention and evaluation, with longer-term outcome follow-ups and exploration of cost-effectiveness of remote delivery of the Positive Health Programme.

Study registration: Current Controlled Trials ISRCTN10697380.

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List of supplementary material

Report Supplementary Material 1 Supplementary material - research governance and procedures

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/KKDS6622).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

ABC	antecedents, behaviour, consequences
A&E	accident and emergency
BSA	British South Asian
CACE	complier average causal effect
CBT	Cognitive Behavioural Therapy
CI	confidence interval
CO-I	co-investigator
COVID-19	coronavirus disease discovered in 2019
CRN	Clinical Research Network
CSO	Clinical Studies Officer
DSM-5	*Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition)
EPDS	Edinburgh Postnatal Depression Scale
EPQ	Economic Patient Questionnaire
EQ-5D-3L	EuroQol-5 Dimensions, three-level version
GAD-7	Generalised Anxiety Disorder Assessment-7
GCP	good clinical practice
GCSE	General Certificate of Secondary Education
GP	general practitioner
HEI	Higher Education Institute
HRA	Health Research Authority
HRDS	Hamilton Depression Rating Scale
HTA	Health Technology Assessment
IAPT	Improving Access to Psychological Therapies
ICC	intraclass correlation
ICD-11	International Classification of Diseases 11th Revision
ICER	incremental cost-effectiveness ratio
IPT	interpersonal therapy
IPV	interpersonal violence
IQR	interquartile range
IRAS	Integrated Research Application System
LCRN	Local Clinical Research Network
MAHSC CTU	Manchester Academic Health Sciences Centre-Trials Coordination Unit
MAR	missing at random
MCAR	missing completely at random
MRC	Medical Research Council
NICE	National Institute for Clinical and Care Excellence
NIHR	National Institute for Health and Care Research
NMR	net monetary benefits
NNT	number needed to treat
NW	North West England
ONS	Office of National Statistics
OR	odds ratio
PHE	Public Health England
PHP	Positive Health Programme
PHQ-9	Patient Health Questionnaire-9
PI	principal investigator
PIS	participant information sheet
PND	postnatal depression
PPI	patient and public involvement
PPIE	patient and public involvement and engagement
PSCS	Parenting Sense of Competence Scale
PSSRU	Personal Social Services Research Unit
PTSD	post-traumatic stress disorder
QALY	quality-adjusted life-year
RCT	randomised controlled trial
REC	Research Ethics Committee
SCAN	Schedules for Clinical Assessment in Neuropsychiatry
SCID	Structured Clinical Interview for DSM-IV
SD	standard deviation
SFA	social functioning assessment

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SUR	seemingly unrelated regression	UKNSC	UK National Screening Committee
TAU	treatment as usual	WHO	World Health Organization
TFA	Theoretical Framework of Acceptability	WTP	willingness to pay
ToC	theory of change		

Plain language summary

The rates of British South Asian women experiencing depression after the birth of a baby are high, causing negative consequences for them, their infants, and their families, with huge costs to society. Due to language and cultural barriers, access to appropriate healthcare services is inadequate for many South Asian women.

The study compared a talking treatment for postnatal depression developed specifically for British South Asian women called the Positive Health Programme, in a group setting, to usual treatment. The aim was to find out if it worked and if it was value for money. Women aged 16 years and over, who were depressed, with a child up to 12 months, were included in the study. We wanted to find out if these women recovered from depression at end of intervention and stayed well for 12 months. We carried out detailed interviews to find out if the talking treatment could be delivered in National Health Service.

A total of 732 participants across four study centres took part in the study. These were allocated completely by chance to either the Positive Health Programme arm or the treatment-as-usual arm. At the end of intervention (approximately 4–6 months), we found that more women in the Positive Health Programme group recovered compared to the treatment-as-usual group. By 12 months, we found that the Positive Health Programme group women continued to stay well, but by that time the women in the usual treatment group also recovered and there was no difference between the two arms of the study.

The results are promising, as more women in the Positive Health Programme group recovered quickly. The study has helped us to understand how to best engage with British South Asian families. We will make recommendations to the people who make health policies for availability of culturally sensitive treatment options for British South Asian women having depression after giving birth.

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Scientific summary

Background

Postnatal depression (PND) is considered the leading cause of disease burden for women of childbearing age and is a global public health priority. It is often underdiagnosed and under-treated. Low mood, referred to as 'baby blues', presents as feeling stressed, weepy, lonely, tired, having mood spells, changes in appetite, and insomnia. It is common for women to experience these feelings following the birth of their baby, but these are usually mild and transient. PND is more severe than the 'baby blues' and symptoms usually develop within the first few weeks after giving birth, and can last up to a year after having a baby. PND is defined as a non-psychotic depressive episode meeting standardised diagnostic criteria for a minor, or major, depressive disorder.

Literature suggests British South Asian (BSA) women have high rates of PND but are less likely to receive treatment compared to the White British women population. High rates of PND may be due to social isolation, financial problems, discrimination, deprivation, being a migrant, language difficulties and, most importantly, inequity in access to health care. Women of ethnic minority backgrounds are less likely to seek help from a general practitioner (GP) to discuss mental health issues compared to White British, and evidence about perinatal mental illness in the UK, which includes PND, is based largely on research among white women.

Cultural sensitivity is required to meet the social, cultural and linguistic needs of patients. Research findings from experiences of PND in BSA women have shown that the women often experience 'culture clash', feelings not being understood by healthcare professionals, and there are thus considerable challenges in reporting mental health symptoms. Prajapati and Libeling have cited literature which suggests that, compared to other ethnic groups, GPs are also less likely to recognise mental health difficulties in the South Asian population and, even after recognition, are less likely to refer them to specialist services. Referrals for South Asian primary care patients for talking therapies are also less likely, despite patients reporting a preference for these over psychotropic medications.

The National Institute for Health and Care Excellence emphasises the need to improve access to care for ethnic minorities and tailor health services to make them culturally sensitive to people's cultural identity or heritage. Psychological therapies need to be adapted to improve engagement with people from ethnic minorities. This could facilitate a better understanding of mental health conditions, diverse explanatory models, and idioms of distress, and may improve access and engagement. Failing to understand the implications of ethnicity and culture on mental health can impact the engagement with services with significant cost implications.

Research supports psychological interventions such as Cognitive Behavioural Therapy (CBT) as an effective treatment for PND and is recommended as a first-line treatment. A recent meta-analysis and systematic review of systematic reviews reported CBT to be the most effective evidence-based psychological treatment for PND. The CBT-based interventions for PND are grounded in the theory that thoughts are the key to understanding emotional and behavioural responses to certain situations and that thoughts are often based on a person's previously held experiences and beliefs. Wenzel and Kleiman propose that beliefs, which are manifested through automatic negative thoughts, are activated during stressful periods, including going through transitions or changes and therefore play a key role in the development and maintenance of PND.

The access to psychological interventions for ethnic minority patients, remains limited, despite the Improving Access to Psychological Therapies (IAPT) initiative. Systematic reviews demonstrate the potential role of group CBT as an alternate solution to address access barriers, by utilising an approach where a single therapist offers CBT to a group. But there is limited evidence for the effectiveness of this approach in ethnic minority women, and it requires further research.

Aims and objectives

This study aimed to evaluate the clinical and cost-effectiveness of a culturally adapted group psychological intervention [Positive Health Programme (PHP)] in primary care for BSA women with PND compared with treatment as usual (TAU).

The objectives of the quantitative study

To evaluate the short-term and long-term clinical and cost-effectiveness of the PHP intervention on rates of recovery from PND in BSA women compared to TAU.

The primary outcome

Recovery from depression as measured by the Hamilton Depression Rating Scale (HDRS) (score seven or less) at end of intervention.

Hamilton Depression Rating Scale

The HDRS was administered to measure the severity of depression at 4 months (end of intervention) and 12 months (Hamilton MA. Development of a rating scale for primary depressive illness. *Br J Soc Clin Psychol* 1967;**6**:278–96). The HDRS has been reported to give valid and reliable results in primary care; we have used the HDRS in Manchester with BSA women, in the Research for Patient Benefit (RfPB) exploratory trial, and in Pakistan.

Objectives of qualitative study

1. To examine the acceptability of the group intervention from the perspective of BSA women and their families.
2. To explore the views of the GPs about the group psychological intervention and its impact on practice.
3. To explore the perspectives of PHP group facilitators (group psychological intervention deliverers) about training and delivery of the intervention.

Methods

Design

A multicentre randomised controlled trial (RCT) with a built-in internal pilot and partially nested design to compare TAU-plus-PHP with TAU in BSA women with PND. Participants were randomised via a remote telephone randomisation service, The Manchester Clinical Trials Unit. Nested qualitative studies explored participant, health professional and facilitator perspectives. An additional substudy was incorporated following the pandemic to explore the impact of other associated risk factors related to maternal mental health and specifically in the pandemic's context. We aimed to increase the understanding of the pandemic-related impact on BSA women, including interpersonal violence (IPV) in their communities.

Setting

Participants were recruited from general practices and children's centres in areas of high BSA density in the North West, East Midlands, Yorkshire, Glasgow and London between February 2017 and March 2020.

Target population

British South Asian women meeting the *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) (DSM-5) depression criteria, aged 16 years or above, and having an infant aged up to 12 months.

Health technology being assessed

Positive Health Programme, a culturally adapted group intervention, based on the principles of CBT. The manual-assisted intervention has been designed to be delivered by non-specialist mental health professionals. The PHP is a 12-session intervention, approximately 90 minutes each, and its feasibility and acceptability has previously been established.

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Measurement of costs and outcomes

The primary outcome was recovery from depression (HDRS ≤ 7) at 4 months (end of intervention). The analysis of the primary outcome and the long-term follow-up (at 12 months) used a logistic random-effects model to estimate the odds ratio of caseness between treatments, adjusting for centre, severity of depression and education at baseline. Cost data were collected using the Economic Patient Questionnaire (EPQ).

For the primary outcome, recovery from PND at 4 months, we found a significant effect such that the odds of achieving recovery in the PHP added to TAU group were almost twice as high compared to the TAU group (OR 1.97, 95% CI 1.26 to 3.10). The improvement was sustained till 12 months in the PHP-plus-TAU group but there was a significant improvement with the TAU group and there was no significant difference in the odds of recovery at 12 months between the PHP-plus-TAU group compared to the TAU group.

Qualitative results

The qualitative study provided indicators of the feasibility and acceptability of the PHP intervention, highlighting underlying processes and contextual influences. The PHP participants, facilitators, and the GPs perceived the intervention as feasible and acceptable. The perceived benefit of increased social relationships during the PHP sessions could have provided an influential therapeutic factor.

The engaging activities that participants found enjoyable and meaningful and discussion and information that resonated with their cultural experience may also have contributed to improvement. Awareness and action to support and improve their low mood and depression were necessary to increase participants' understanding and build their coping skills. Improved emotional and social support, better coping strategies, and an enhanced sense of well-being demonstrate the mediating variables between PHP and the reduction of depression. In addition, the culturally adapted PHP intervention content enabled intervention delivery and was positively received by the PHP participants. The qualitative data supplemented the trial outcomes and provided a contextualised description of how PHP contributed to reduction of depression.

Economic evaluation

The PHP was estimated to cost an average of £408 per participant. The intention-to-treat analysis shows that the PHP intervention costs £22,198 per quality-adjusted life-years (QALYs) gain. PHP was cost-effective on average but with a substantial uncertainty: the probability that PHP would be cost-effective is 44% (65%) if the policy-makers are willing to pay £20,000 (£30,000) per QALY gain. PHP was highly cost-effective for those who attended 5–8 sessions, costing £9040 per QALY gained.

Conclusions

We consider that the results of this study provide robust evidence that the culturally adapted psychological intervention PHP is clinically effective at the primary end point. The results are promising for the wider field, particularly for learning lessons in engagement with this community. This study has led to multidisciplinary deliberations on a broader level across the UK, focusing on the culturally adapted method of engagement and delivery tailored explicitly for 'hard-to-reach' communities. The ethnic minorities community is often labelled as 'hard-to-reach' or as 'easy-to-ignore' as phrased by one of the community partners. Despite a number of policy initiatives, the services lack the uptake of tailoring their approaches to the community they serve, and the level of cultural engagement is limited. The creative methods of recruitment, engagement and commitment to engage with the community to enhance participation in research can serve as a best-practice example for recruitment in future similar studies. The results suggest that some form of maintenance contact and booster PHP sessions, possibly digital within the 1-year period, could be helpful. The focus of future research should be further development of the PHP intervention and evaluation, with longer-term outcomes. The positive results of transition to remote delivery of PHP observed during the pandemic may be a cost-effective way forward.

Study registration

Current Controlled Trials ISRCTN10697380.

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Chapter 1 Background

Postnatal depression

Postnatal depression (PND) is considered the leading cause of disease burden for women of childbearing age,[1] and is a global public health priority. It is often underdiagnosed and under-treated.[2] Low mood, referred to as 'baby blues', can present as feeling stressed, weepy, lonely, tired, having mood spells, changes in appetite, and insomnia. It is common for women to experience these feelings following the birth of their baby,[3] but these experiences are usually mild and transient. PND is more severe than the 'baby blues' and symptoms usually develop within the first few weeks after giving birth and can last up to a year after having a baby. PND is defined as a non-psychotic depressive episode meeting standardised diagnostic criteria for a minor, or major, depressive disorder.[4]

The two key universal classifications, The International Classification of Diseases (ICD-11)[5] and *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition) (DSM-5),[6] provide the standards for the measurement of depression. In the ICD-11,[4] episodes are assessed as mild, moderate, or severe depending on the severity of the depressive symptoms and the degree of functional impairment. Nine symptoms of depression are identified in the DSM-5.[5] The standard for a major depressive disorder in DSM-5 requires the identification of either (1) depressed mood most of the day, on a daily basis, with individuals reporting hopelessness, worthlessness, or appearing weepy; or (2) noticeably less attentiveness or desire, alongside at least five of the symptoms, for at least 2 weeks (criteria include: weight loss or gain, insomnia or hypersomnia, psychomotor agitation or retardation, fatigue, feeling worthless or excessive guilt, poor concentration and thoughts of death/suicide). The severity of postnatal depression can vary and can present with the symptoms of both major and minor depression as defined in the DSM-5.

Neither of the two classification systems, the ICD-11 or the DSM-5 provide explicit categories for PND. However, the ICD-11 endorses that depression in the postnatal period could be grouped as one of the usual categories of depression. Nonetheless, if the symptoms do not fall into the other criteria for depression, there is a clause for a mental disorder arising within 6 weeks of the delivery. Specifiers such as 'with peripartum onset' are within the DSM-5, which denotes similar symptoms connected with major depression, however, uses the most current episode arising during pregnancy and the 4 weeks after delivery. The revision in DSM-5, from DSM-IV,[7] is essentially related to the introduction of the postpartum specifier compared to the earlier version, which recognised PND as a mental disorder beginning within 6 weeks of the delivery. However, the latest revision has still not extended the period following delivery and considers the most recent depressive episode until only 4 weeks after having the baby. Evidence suggests that the DSM-5 specifier is restrictive, as clinicians deliberate that depressive episodes in the perinatal period can occur at any time within a year after birth.[8]

Epidemiology and risk factors of postnatal depression

A comprehensive overview of the global epidemiology of PND indicated that PND was found in 17.22% of the female population.[9] Anxiety, comorbid with depression and on its own, is also common during the postpartum period. During the perinatal period the prevalence of any type of anxiety disorder has been estimated to be between 4% and 20%.[10,11] Trajectories of maternal postnatal depressive symptoms suggest these symptoms reduce within a few months from onset,[12] but approximately 30% of women continue to have depression beyond the first year after delivery and are at high risk (40%) of subsequent postnatal and non-postnatal relapse.[13]

The incidence of mental health problems during the perinatal period may increase depending on circumstances and, therefore, have significant implications for the care provided. The latest findings from the National Maternity Survey for women who gave birth in England during the first wave of the COVID-19 pandemic in 2020 highlight an increase in anxiety during pregnancy and an increase in both anxiety and depression in the postnatal period. This increase in mental health problems was significantly higher when compared to findings from National Maternity Surveys conducted in previous years.[14]

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The UK is a multiethnic society, and its population's diversity continues to increase.[15] Data from the Office for National Statistics[16] indicate that 7.5% of the total population is classified as 'South Asian', making it the largest ethnic minority. 'South Asian' is defined as people with origins from India, Pakistan, Bangladesh, Nepal, Bhutan and Sri Lanka who share familial or cultural backgrounds.[17] In 2019, UK migrants mostly originated from India and Pakistan.[18]

Ethnicity and culture are considered to have an impact on how and when women seek help for mental health problems during the perinatal period, and many women are reluctant to go for a professional consultation because they feel the services available are not sensitive to their beliefs.[19] Some ethnic minority groups in the UK have a higher burden of mental health disorders, including anxiety and depression, as compared to the majority white population.[20,21] There is also a lesser likelihood of these disorders being detected or treated, including during the perinatal period for people from minority ethnic backgrounds.[22,23] In British Pakistani women living in the North West of England the rate of perinatal depression assessed using the Schedules for Clinical Assessment in Neuropsychiatry (SCAN)[24] was 17% during pregnancy and 19% during the postnatal period.[25]

The target population of the study was British South Asian (BSA) women with postnatal depression and psychosocial difficulties. As mentioned above, ethnic minority groups, particularly women of South Asian origin, are at higher risk for developing PND.[26,27] A secondary analysis of birth cohort data and linked routine care data in the UK by Prady *et al.*[22] found an estimated prevalence of between 9.5% and 14% for common mental disorders (CMD) in British women pre birth. It was found that compared to White British and White Irish populations, the prevalence of PND was significantly higher among South Asian women.[24,28] A recent report on maternal mental health and well-being during the COVID-19 pandemic, published by the Centre for Mental Health,[29] addressed the disparity in maternal mental health outcomes caused by the crisis and outlines how the impact has been unequal.

Additional risk factors of PND are provided in an updated umbrella review,[30] a synthesis of the systematic reviews and meta-analyses focused on risk factors for PND over the past 20 years. The review identifies 25 statistically significant risk factors for PND, including high life stress, lack of social support, current or past abuse, PND, and marital or partner dissatisfaction. These risk factors, particularly marital difficulties, are high in British South Asians.[31,32] Lesser-known risk factors, but equally important, include lifelong depression in the spouse, younger than 20 years, worries related to lack of access to child care, previous miscarriage and birth defects in the baby.[33]

Personal, social and economic costs of postnatal depression

The impact of PND on well-being is well established[34] and includes increased risk of chronic disease and substance misuse, breastfeeding problems, poorer quality of life, relationship problems, increased risk of suicide, as well as the economic burden of loss of earnings and unemployment.[35,36] A recent systematic review on the consequences of PND on maternal outcomes[37] suggests that PND creates an environment that is neither conducive to women's personal development nor for the baby's optimal growth and development. Maternal mental health problems can negatively impact women's capacity to provide care for young children when they are most sensitive to their environments, leading to behaviour difficulties, impaired cognitive and emotional development outcomes for children, and insecure attachment.[38,39] Infants before the age of 1 year, with women experiencing PND, are at a higher risk of developmental vulnerability at school entry.[40]

Women from an ethnic minority are more likely to have preterm and low-birthweight babies and often receive late or no prenatal care compared to the majority white women.[41] The COVID-19 pandemic has highlighted the urgent need to address disparities faced by ethnic minority groups in maternal and infant health specifically and the importance of providing culturally competent care.[42] As stated above, supporting maternal mental health during the postnatal period is crucial for strengthening the well-being of women and reducing the impact of depression on intergenerational transmission of adversity.[43]

The report 'The Costs of Perinatal Mental Health Problems'[44] commissioned by the Maternal Mental Health Alliance[44] suggested that in addition to the human suffering, mental health problems during the perinatal period (period between pregnancy and first year postnatal) carry a total long-term cost to the society. Calculated conservatively in the UK, the

cost is more than £8,1B each year. The report highlights that approximately half of all cases of perinatal depression and anxiety are overlooked, and those identified frequently fall short of benefiting from evidence-based treatment. Since the report's publication,[43] the UK has substantially invested in addressing the needs of women with perinatal mental health problems as part of the Five Year Forward View and additional funding commitment in the NHS Long-term Plan.[45] However, major gaps remain, particularly related to making appropriate referrals and supporting women who do not meet the threshold of severity of depression, which, if left untreated, may become more severe in the long term.[46]

A recent report, 'The economic case for increasing access to treatment for women with common mental health problems during the perinatal period', by the Care Policy and Evaluation Centre and London School of Economics and Political Science,[47] emphasises the need for new service models. The need is even stronger now, due to the significant increase in demand for maternal mental health services during the COVID-19 pandemic.[48] These findings necessitate greater investment in improving maternal mental health services since they provide a clinically effective and cost-effective solution with a potential to improve the lives of the women in this generation but has benefits for the next generation.

Current service provision in the United Kingdom

The National Institute for Health and Care Excellence (NICE) guidance for antenatal and postnatal mental health[49] in the UK outlines the recommended care pathway for recognition, assessment, care, and treatment for women with PND, up to 1 year after childbirth. The guidelines suggest that at a woman's first antenatal contact with primary care, and then during the early postnatal period (usually at 4–6 weeks and 3–4 months), healthcare professionals should routinely consider asking two questions ('During the past month, have you often been bothered by feeling down, depressed, or hopeless?' 'During the last month, have you often been bothered by having little interest or pleasure in doing things?') to screen for depression as part of a general discussion about a woman's mental health and well-being. If a woman responds positively to the questions, she should be considered at risk of developing a mental health problem. Alternatively, if there is a clinical concern, the use of either the Edinburgh Postnatal Depression Scale (EPDS)[50] or the Patient Health Questionnaire-9 (PHQ-9),[51] as part of a full assessment, is recommended[48] to assess severity of problems.

In case of identification of a mental disorder, either during pregnancy or the postnatal period, NICE guidance[48] recommends additional assessment, including referral to the GP for further assessment and management. Targeted psychosocial interventions are recommended for women who have symptoms of depression or anxiety but do not meet the threshold for a formal diagnosis. NICE[48] further recommends that for women with a moderate depressive episode or a history of depression, or those with a severe depressive episode during pregnancy or in the postnatal period, high-intensity psychological treatment specifically for depression [cognitive–behavioural therapy (CBT) or interpersonal therapy (IPT)] [Improving Access to Psychological Therapies (IAPT) service] should be considered. Antidepressants should be considered for women with severe depression, and those with mild/moderate depression but not responding to psychological treatment. The antidepressants need to be prescribed cautiously[52] and evidence suggests that women may be reluctant to take psychotropic medications and prefer non-pharmacological treatments, particularly while breastfeeding.[53,54] It is recommended[51] that when a woman with a known or suspected mental health problem is referred during pregnancy or the postnatal period, assessment for treatment within 2 weeks of referral and psychological interventions within 1 month of initial assessment should be provided.

Barriers to help-seeking for women with postnatal depression

The NICE guidelines on antenatal and postnatal mental health recommend that women be asked specific depression identification questions at their first contact with primary care or their booking visit. The findings indicate an estimated 31–46% cases of perinatal depression are missed, suggesting a substantial diagnosis gap and under-recognition in general practice.[55] The gap in diagnosis could be due to a range of factors. For example, women may feel hesitant to share their experience of symptoms with their GP or other primary care clinicians. Reasons include feeling reluctant to acknowledge that they are struggling with their mental health, lack of family support, feeling that they are expected to

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cope on their own, bringing shame and stigma to the family, and having a fear of being labelled and losing their baby. Secondly, when women share their symptoms, GPs or other primary care staff may sometimes not consider it a task within their scope of work, may not follow up or have delayed follow-up, and may not make a formal diagnosis.[56] A further reason for under-recording in GP records could be that GPs may rely on health visitors to address these aspects of care and when this is not communicated by the health visitors to the GPs, it does not go into primary care records. The fragmented nature of postnatal care, involving several healthcare professionals, could be one of the reasons for missed or delayed identification, as reported by Silverwood *et al.*,[57] for perinatal anxiety.

A report on maternal mental health[52] suggested that most of the women who reported experiencing mental health difficulties were not referred to relevant services or given any advice about which organisations they could contact to seek further help. Lack of cultural sensitivity and other associated factors have also been identified as help-seeking barriers for women with PND. South Asian families may discourage women from seeking help and discussing concerns, such as mental health problems with people external to the family.[58] Evidence suggests that the perinatal needs of women from ethnic minority groups are met less often than White British women.[53,59]

Postnatal depression in British South Asian women

The BSA population continues to be the largest and fastest-growing minority ethnic group in the UK.[60] Literature suggests BSA women have high rates of PND but less likely to receive treatment compared to the White British women population.[30,61] High rates of PND may be associated with social isolation, financial problems, discrimination, deprivation, being a migrant, language difficulties and most importantly, inequity in access to health care.[62] Women of ethnic minority backgrounds are less likely to seek help from the GP to discuss mental health difficulties compared to the majority White British[18] and evidence about perinatal mental illness in the UK, which includes PND, is based largely on research among white women.[58]

Cultural sensitivity is required to meet the social, cultural, and linguistic needs of patients.[63] Research findings from experiences of PND in BSA women has shown that the women often experience 'culture clash', feeling misunderstood by healthcare professionals, and consequently considerable challenges in reporting mental health symptoms.[64] Prajapati and Libeling[17] suggest that, compared to other ethnic groups, GPs are also less likely to recognise mental health difficulties in South Asian people and, even after recognition, are less likely to refer them to specialist services. Referrals for South Asian primary care patients for talking therapies are also less likely, despite a preference over psychotropic medication.[31]

British South Asian women are often considered to be underserved and 'hard-to-reach' due to language and cultural barriers.[27] Many BSA women lack fluency in English and the resources to obtain help[60] and these barriers when accessing psychological services are even greater. Leaving symptoms of maternal depression unrecognised and untreated increases the risk both to the women and their infants of poorer health outcomes.[16,65] Karasz[66] investigated explanatory models of illness and demonstrated that South Asian women interpreted depressive symptoms to be because of situational stress, compared to white women who attributed PND symptoms to hormonal imbalance or biological factors. Such explanatory models may be more responsive to psychosocial approach, but may be difficult to negotiate due to difficulties in communication, cultural stereotypes held by healthcare professionals, little information about culturally sensitive treatment pathways, or differences in explanatory models between the physician and the ethnic minority patients leading to less likelihood of being referred for psychological interventions.[67]

Research demonstrates that South Asian women experience high rates of interpersonal relationship problems compared to the majority White British.[19,30] As mentioned above within the South Asian community, the concept of stigma, shame and the notion of maintaining family honour – 'Izzat' – can make women feel reluctant to discuss and disclose symptoms of PND or access psychological services.[68]

The need for cultural adaptation of psychological treatments

The NICE[48] emphasises the need to improve access to care for ethnic minorities and tailor health services to make them culturally sensitive to people's cultural identity or heritage. Psychological therapies need to be adapted to

improve engagement with people from ethnic minorities.[69] This could facilitate a better understanding of mental health conditions, diverse explanatory models and idioms of distress, and may improve access.[70] Failing to understand the implications of ethnicity and culture on psychological health can impact the engagement with services,[71] and this also has cost implications.[68]

Empirical research supports psychological interventions such as CBT as an effective intervention for PND and is recommended as a first-line treatment.[48] A recent meta-analysis and systematic review of systematic reviews reported CBT to be the most effective evidence-based psychological treatment for perinatal depression.[72] CBT-based interventions for PND are grounded in the principle that cognitions are the key to understanding emotional and behavioural reactions to certain situations and that cognitions are typically based on a person's previously held experiences and beliefs. These are manifested through automatic thoughts, which further influence a person's emotional and behavioural reactions.[73,74] Wenzel and Kleiman[74] propose that beliefs, which are manifested through automatic negative thoughts, are activated during stressful periods, including going through transitions or changes, and therefore play a key role in the development and maintenance of PND.

Access to psychological interventions, however, remains limited, despite the IAPT initiative, especially for ethnic minority patients.[75] Systematic reviews[76,77] demonstrate the potential role of group CBT as an alternate solution to address access barriers, by utilising an approach where a single therapist offers CBT to a group. But there is limited evidence for the effectiveness of this approach in ethnic minority women, and it requires further research.

The Positive Health Programme (PHP) was developed as a culturally adapted group CBT intervention for BSA women with PND.[53] PHP was further developed and tested in an exploratory randomised controlled trial (RCT) (ROSHNI-D – NCT01838889[27]). The PHP is a group psychological intervention that uses principles of cognitive–behavioural model and consists of 12 weekly group sessions, that is duration of intervention being 3 months. The approach to addressing cultural barriers to access is partly informed by the Lau *et al.*[78,79] conceptual framework for improving access and cultural adaptation of interventions (*Figure 1*).

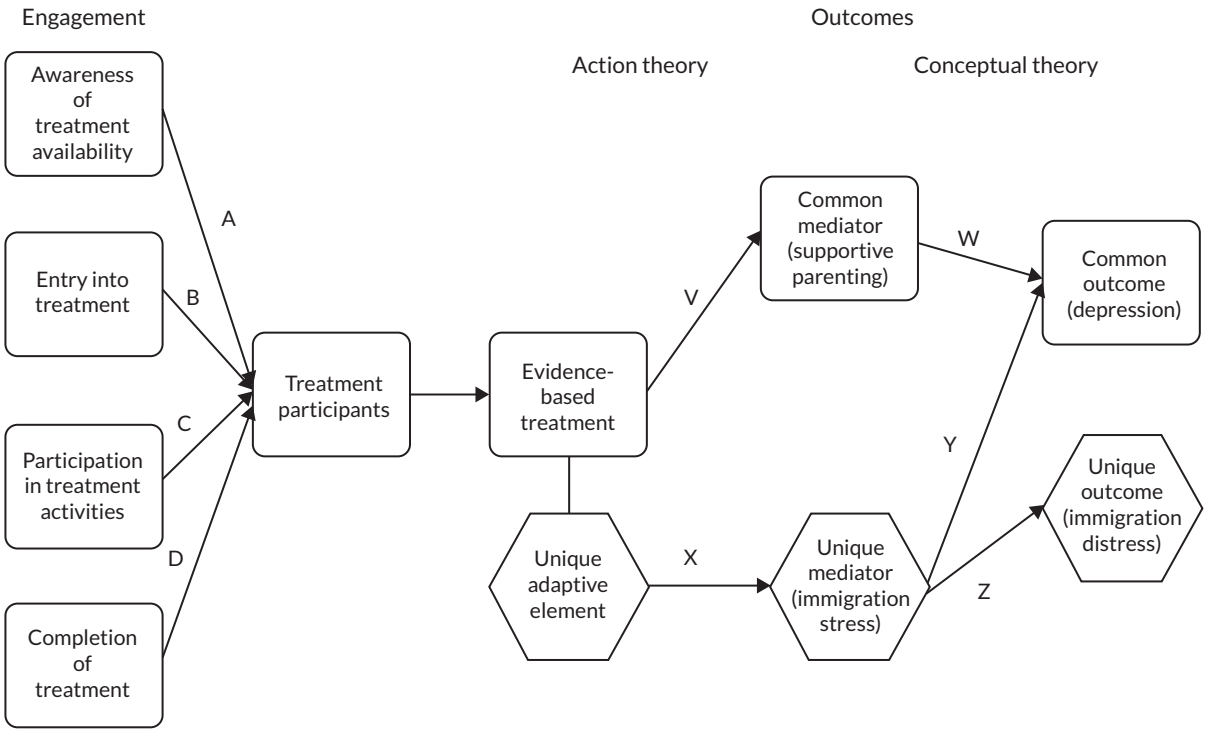

FIGURE 1 A heuristic framework for the cultural adaptation of interventions.

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Earlier studies evaluating culturally sensitive psychosocial group interventions for the treatment of depression in BSA women reported an improvement in depression and participants' self-confidence at the end of the intervention.[19,30,31] Studies suggest[27,31,53,80] the relationship between the facilitator and the participants, and sensitivity to local culture are crucial factors for successful engagement. The content of the group sessions was developed with particular emphasis on developing empathy, maintaining confidentiality, and facilitating engagement.

A total of 83 participants were included in the ROSHNI-D exploratory trial, 42 randomised to the PHP intervention and 41 to the routine treatment. Four PHP groups were completed successfully across Manchester and Lancashire with reasonable attendance (64% of the 42 randomised). The recruitment figures of women screened (n = 560) and trial retention figures, at the end of intervention (80%) highlighted the ability of the research team to engage with the population.[27] The findings of a nested qualitative study within the trial showed that interventions targeting PND in BSA women would need to pay particular attention to ways of improving engagement with the family, self-esteem, social support, independent coping strategies, child care, and transport provision, and using the group discussion and communication techniques (storytelling).

Through the ROSHNI-D trial, we learnt how best to recruit and retain BSA women with PND in an RCT. The recruitment of bilingual research assistants and group CBT facilitators via the NHS, newspaper advertisements and the voluntary sector was innovative, leading to high recruitment and follow-up rates. A larger trial was needed to test the findings of the exploratory trial, to test both short- and longer-term outcomes and to answer additional research questions, including the cost-effectiveness of PHP. The focus of the present trial is to test a group CBT intervention (PHP) for BSA women with PND and psychosocial difficulties, using both quantitative and qualitative methods. The UK Medical Research Council (MRC) recommends that both qualitative and quantitative methods are used to evaluate complex interventions[81] and qualitative data gathered from in-depth interviews with trial participants can provide valuable insight into their experiences of the trial and the intervention.[82] The current trial results will provide evidence for the culturally adapted CBT intervention for BSA women and the importance of cultural adaptation for excluded groups with unmet needs. The results are likely to inform the next update of the NICE PND guidelines.

Chapter 2 Aims and objectives

This study aimed to evaluate the clinical and cost effectiveness of a culturally adapted group psychological intervention (PHP) in primary care for BSA women with PND compared with treatment as usual (TAU).

Diagnosis of depression

The full baseline assessment was carried out after the diagnosis of depression using the Structured Clinical Interview for DSM Disorders (SCID).[83] The interview consists of standardised diagnostic questions arranged in modules corresponding to each DSM-5 Axis I disorder. The SCID has been used in a large RCT of a psychological intervention for PND in a multicultural population in Canada.[84] It was used for assessing PND across seven countries.[85] It has been successfully used in a large (*n* = 900) CBT perinatal depression trial in rural Pakistan.[86]

The objectives of the quantitative study were: To evaluate the short-term and long-term clinical and cost-effectiveness of the PHP intervention on rates of recovery from postnatal depression in BSA women compared to TAU.

The primary outcome: Recovery/remission from depression as measured by a Hamilton Depression Rating Scale (HDRS) score of 7 or less at 4 months (end of intervention).

Hamilton Depression Rating Scale:[87] The HDRS was administered to measure the severity of depression at 4 months (end of intervention) and 12 months. The HDRS has been reported to give valid and reliable results in primary care; we have used the HDRS in Manchester with BSA women,[19] in the Research for Patient Benefit (RfPB) exploratory trial[24] and in Pakistan.[85] The objective is to evaluate the short-term, 4-month (end of intervention) effectiveness of the intervention on rates of recovery from PND . Recovery is a score of 7 or less[88] as measured by the HDRS.[86]

Objectives of the internal pilot qualitative study

1. Explore early barriers/enablers to study participation to optimise ongoing trial recruiter training and trial recruitment rates.
2. Identify reasons for continuing or not continuing with the study.

Objectives of qualitative study for the full trial

1. To examine the acceptability of the group intervention from the perspective of BSA women and their families.
2. To explore the views of the general practitioners (GPs) about the group psychological intervention and its impact on practice.
3. To explore the perspectives of PHP group facilitators (group psychological intervention deliverers) about training and delivery of the intervention.

Success criteria for the internal pilot phase

Success criteria for the pilot were to recruit 200 participants during the internal pilot study phase (months 5–14). The predetermined stop/go criteria were as follows:

- Go if 180 or more participants are recruited into the study (the target minus 10%).
- Implement rescue plan if > 120 (60%) but < 180 (90%) recruited in the study.
- Stop if < 120 (60%) recruited in the study.

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Chapter 3 Methods

Trial design

ROSHNI-2 was designed using a multicentre two-arm, rater-blind RCT. The trial compared a culturally adapted CBT-based intervention (PHP) accompanied by TAU with just TAU for BSA women with PND. The primary outcome point for the trial was at post intervention at 4 months, and further follow-up with assessments (secondary outcomes) was conducted at both post intervention and 12-months after randomisation (*Figure 2*). The study included an internal pilot phase (18 months) with clear stop/go criteria, with the success criteria being set at the recruitment of at least 180 participants.

Study approvals

The study sponsor was Lancashire & South Cumbria NHS Foundation Trust, with the study being approved by the North West Health Research Authority [ethics approval number: Integrated Research Application System (IRAS) 187851; 6 January 2017]. Research management and governance arrangements and approval were acquired for each trial centre subsequently. The study was also registered with the International Standard Randomised Controlled Trial Number (ISRCTN10697380). The Manchester Academic Health Sciences Centre-Trials Coordination Unit (MAHSC-CTU) was subcontracted to provide randomisation services, study monitoring and research auditing.

Trial centres

The trial consisted of study centres in areas with high density of South Asians (*Table 1*). These included North West (Blackburn, Burnley, Accrington, Bolton, Greater Manchester, Preston and Oldham), North West, Yorkshire (Bradford, Dewsbury and Keighley), Midlands (Derby and Leicester), London and Glasgow. Each site had a delegated local principal investigator (PI) lead who was responsible for co-ordinating the recruitment of participants into the trial. Staff at each site had responsibility for the day-to-day running of the trial and engagement with participants.

TABLE 1 Ethnic population density across regions[89]

Region	Asian (%)	Black (%)	Mixed (%)	White British (%)	White other (%)	Other (%)
London	18.5	13.3	5	44.9	14.9	3.4
West Midlands	10.8	3.3	2.4	79.2	3.6	0.9
Yorkshire and The Humber	7.3	1.5	1.6	85.8	3	0.8
East Midlands	6.5	1.8	1.9	85.4	3.9	0.6
North West	6.2	1.4	1.6	87.1	3.1	0.6
South East	5.2	1.6	1.9	85.2	5.4	0.6
East	4.8	2	1.9	85.3	5.5	0.5
North East	2.9	0.5	0.9	93.6	1.7	0.4
Wales	2.3	0.6	1	93.2	2.4	0.5
South West	2	0.9	1.4	91.8	3.6	0.3

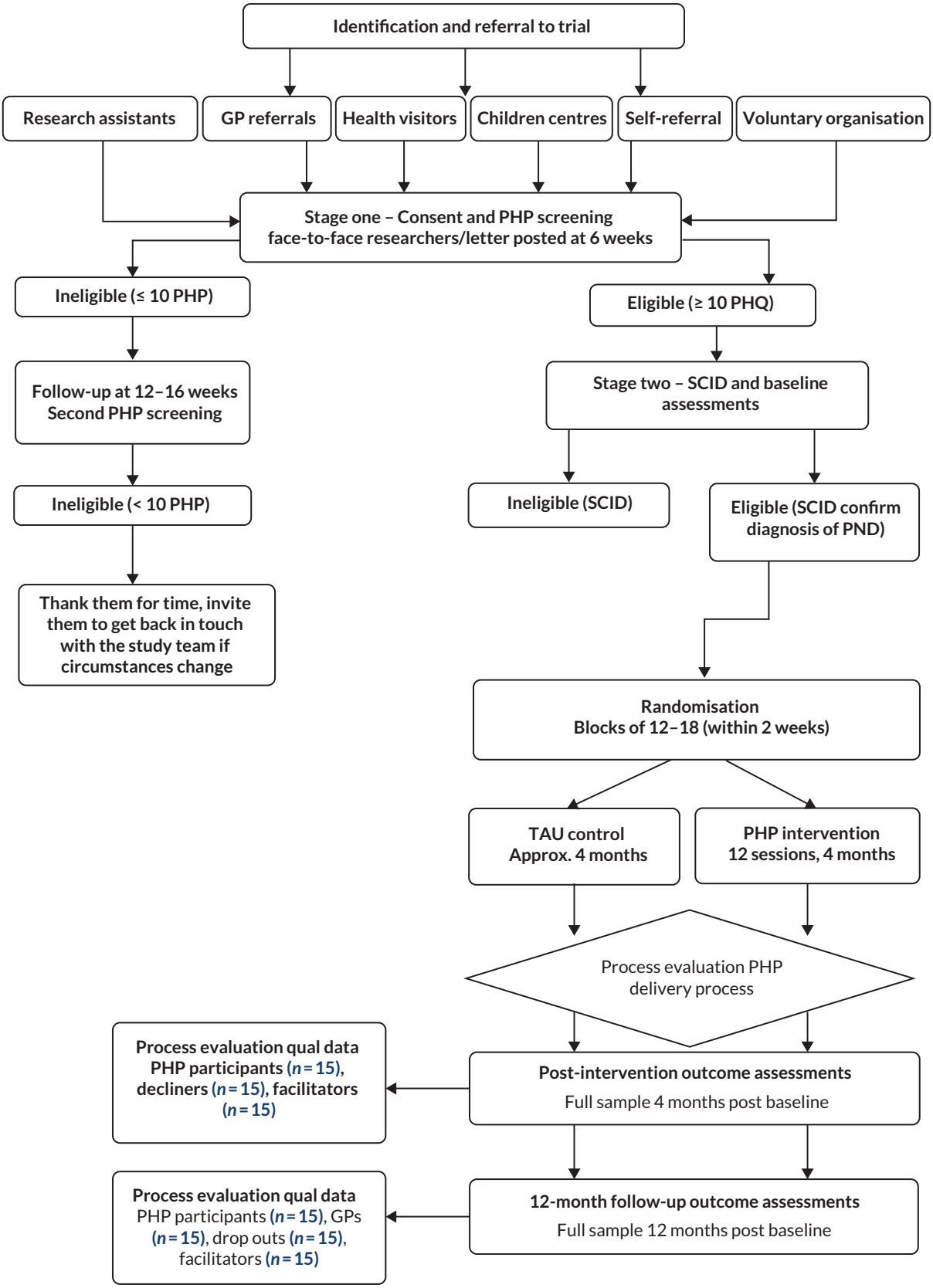

FIGURE 2 Study flow design.

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Participant eligibility

Inclusion criteria

- Self-ascribed BSA women [Office of National Statistics (ONS) ethnicity].
- Aged 16 years or above.
- With a child up to 12 months of age.
- Met the DSM-5 [Structured Clinical Interview for the DSM (SCID)] criteria for depression.

Exclusion criteria

- Any diagnosed physical or intellectual disability limiting ability to provide informed consent as determined by the participants care team, GP, or Chief Investigator.
- Post-partum or other psychosis.
- Actively suicidal.

Antidepressant medication and a prior self-reported common mental illness, including prior PND, were not an exclusion criterion. The clinical history of other types of mental health disorders were determined on a case-by-case basis and was informed by the clinical judgement of clinicians with patient safety and potential participants ability to provide informed consent.

Recruitment strategies developed during internal pilot

Participant recruitment

Potential participants were approached through their local GP surgeries, children's centres, baby clinics, local community and voluntary organisations, pharmacies, nurseries, schools, local faith organisations and through attending community health events. To increase awareness of the study and ensure it reached the targeted audience, we used culturally sensitive public facing materials co-produced through patient and public involvement and engagement (PPIE) input. The materials (flyers, posters, banners and social media campaigns) were produced in English and then, translated into Hindi, Urdu, Tamil, Bengali and Gujarati languages. The research team at each study site engaged with local community and voluntary sector organisations and set up regular liaison meetings with the local health visiting teams, GPs, and children's centres to promote the study. This involved attending meetings to raise awareness about the study, enhance engagement, and build rapport to start valuable conversations on maternal mental health in BSA women. The research team made significant efforts to engage GP practices and initiated lunch-and-learn sessions at GP practices and attended business meetings to build rapport and engage with primary care teams. Each site had multilingual research assistants appointed to work on the study who also identified as British South Asian and were trained in cultural sensitivity when working in this context.

Media involvement

The study team worked closely with the media consultant Shakil Salam to promote the study using BSA media. During the pilot period, the Chief Investigator, deputy manager and other research team members made TV appearances on local South Asian TV channels and radio stations. The study team also recorded a radio advert aired across North West from November 2017 onwards; the advert was in both English and Urdu. There were press releases in both local and national newspapers in English and South Asian languages. The CI was interviewed on BBC Radio 5 live to talk about ROSHNI-2 for their maternal mental health summit during the pilot period.

General practices and children's centres

The research team continued to work closely with primary care and children's centres, as these were the key recruiting sites. Regular updates were shared with the GP practice managers, and the research team ensured active engagement by sending e-mails on special occasions, such as Eid and Diwali.

Training and development

Opportunities were created for bilingual volunteers to support the ROSHNI-2 study. The volunteers participated in training away days, including how best to recruit participants to ethnic minority trials delivered by co-app WW. There was also a session on successful recruitment and retention in perinatal mental health trials led by Professor Cindy-Lee Dennis from the University of Toronto and general day-to-day delivery of the trial. There was regular PHP training conducted by the study management team and supervision sessions. A total of 45 facilitators were trained across the sites for the full 2-day training and refreshers. Twenty-two of these delivered PHP sessions across sites. The training was offered widely across the community to develop capacity in psychological therapies and promote a culturally adapted model of delivery and engagement.

Cluster strategy

Across all study centres, 'clusters' with high South Asian density areas and birth rates were identified so that the research team could focus all their efforts on these clusters for maximum primary care and community engagement. A 'cluster' was an area mapped out, capturing approximately potential 350 South Asian women to be invited to the study. Given a conservative 10% rate of depression, we anticipated 35 women being eligible for the study on PHQ-9 (high scorers). Of these 35, we anticipated 12–18 being eligible for randomisation giving us one randomisation group (6–9 mums in intervention and 6–9 mums in TAU).

Recruitment to the main trial

The strategies developed during the internal pilot were incorporated into the recruitment process through the main trial. We ensured that we implemented lessons learnt from our previous work[27,53] with BSA women with PND and the internal pilot. We engaged with women's families (with consent) from the initial screening stage to ensure participation and continuity in the study. Contact details of bilingual senior members of the team were provided to family members for any queries. Further information on the research team's recruitment engagement efforts is published elsewhere.[90] The recruitment period was between February 2017 and March 2020.

Amendments were made as a result of learning from the internal pilot, feedback from the advisory group's PPIE work, and the addition of sites to maximise patient recruitment and retention to the trial. Amendments included adding in a child development measure, new sites, reducing group sizes for randomisation, and more engaging promotional materials. Full details of the amendments can be referred to in the attached *Report Supplementary Material 1*.

Recruitment via general practitioners

Participating GPs sent invitation letters to all British South Asian women who were 6 weeks post natal with study information and an invitation to participate in the study. The invitation note included the PHQ-9[50] (in Urdu and English), a participant information sheet (PIS), a return form for consent to contact and a stamped return addressed envelope. An additional slip was included which asked participants to contact the study team if they required the information in another language, this statement was in all five study languages. Interested participants were instructed to populate the PHQ-9 questionnaire and complete the consent-to-contact form, and requested to post the completed documents to the research team at their allocated study site. Reminders were followed up via post and telephone for those who did not respond within 4 weeks. Furthermore, GP records were examined for non-responders, and the primary care staff (health visitors and community midwives) were asked to include reminders about the study during their routine visits.

Research assistants contacted all women who fulfilled the trial eligibility criteria, completed consent-to-contact forms, who scored 10 or more on the PHQ-9. The potential participants were then contacted to provide further information and invited to provide written informed consent for trial participation and baseline assessments. A mutually convenient meeting time and location (general practice, children's centre or at home, or over the telephone) was arranged with the potential participant to obtain informed consent and discuss any queries raised. All potential participants were given sufficient time to consider participation (up to 48 hours) before signing the consent form.

In addition, the research team had ethics approval and permission from the GPs to work with practice staff to access routine health records, and to identify potential participants eligible for the study. This activity was carried out by general practice administrative staff or NIHR Clinical Research Network (CRN)-funded Clinical Studies Officers (CSOs). Once identified, potential participants were contacted either by phone or in person by the CSO, research nurse or

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administrative staff to obtain consent to contact for the research team. The research team also attended local children's centre, baby clinics, mums' support groups and playgroups to meet with potential participants, shared information about the study and provided interested individuals with a PIS.

Recruitment via baby clinics

Participants were also approached by trained researchers for the study in person at GP clinics and children's centres. The study PIS was explained to each potentially eligible participant and consent obtained. After obtaining consent from participants, the PHQ-9 was administered by a research assistant, with participants scoring 10 or more progressed to the second eligibility assessment stage. All low scorers on the PHQ-9 at the first screen who had consented were invited to complete a further PHQ-9 after 12–16 weeks to ensure that later-onset PND was not missed. All assessments were conducted in Urdu, Hindi, Bengali, Gujarati and Tamil based on participant preference. On first contact participants were asked what their language preference was and, based on this, the Research Assistant (RA) would be allocated to complete their screening/baseline/follow-up assessments.

Baseline assessment

Individuals who agreed to proceed with the study were taken through the informed consent procedure for second-stage screening to confirm the diagnosis of depression. Diagnosis of depression was confirmed using SCID.[82] The SCID has been used in a multicultural population in Canada.[83] To meet research diagnosis on the SCID, participants had to score a three on either the depressive symptoms (Question 1) or the work and activities (Question 2). In addition to either of these two, they needed to score a 3 on any three items giving a total of five positive scores on the SCID. Further details on the SCID are described in *Chapter 6*. Participants who scored positively on the SCID were also asked to complete a range of additional outcome measures, which consisted of:

- Demographics – information such as age, ethnicity, language spoken, marital status, employment status and qualifications.
- The HDRS[86] treatment response criterion is a reduction of ≥ 50% in the HDRS baseline score of the participants. In this study, the 17-item version was used and integrated within the SCID assessment. The measure has been validated in the Urdu language.[91]
- PHQ-9 items:[50] valid and reliable self-report measure of severity of depression; Urdu and Bengali versions of the PHQ-9 have been validated.[92] A higher score corresponds to more severe depressive symptoms.
- Generalised Anxiety Disorder-7 (GAD-7):[93] a valid and reliable self-report measure of severity of anxiety; an Urdu version of the GAD-7 has been validated.[94] A higher score corresponds to more severe anxiety symptoms.
- Parenting Sense of Competence Scale:[95] a valid and reliable self-report measure of parental competence;[96] Parental competence is measured on two dimensions of satisfaction and efficacy the questionnaire has 16 items (9 on satisfaction and 7 on efficacy) and is scored according to a 6-point Likert scale, ranging from '1, strongly disagree' to '6, strongly agree'. A higher score corresponds to better parenting sense of competence.
- Social functioning: a self-report measure rating difficulty in completing a 10-item measure of daily function. The questionnaire is scored according to a 5-point Likert scale, ranging from '0, no difficulty' to '4, often can't do the task'. A higher score demonstrates a higher social dysfunction.
- Ages and stages questionnaires:[97] a valid and reliable parent-completed measure of childhood development; this series of 11 questionnaires each include 30 closed questions on 5 domains of child development; trial participants completed the questionnaire both at baseline and 12-month follow-up. Higher scores indicate better child development, generally scores above 40 suggest that the child's development is on schedule.
- EuroQol-5 Dimensions, five-level version[98,99] is a health status measure, which has five dimensions (mobility, self-care, usual activity, pain/discomfort, anxiety/depression); participants can rate themselves as having no problems, some or moderate problems or extreme problems (for pain/discomfort and anxiety/depression domains), or unable to do an activity (self-care) and usual activity domains or confined to bed (mobility domain).
- Economic Patient Questionnaire (EPQ): health service use data were collected using the EPQ; in addition to the NHS and social care. The cost to the participant for services was collected by capturing information from participants in both arms of the trial that accessed any other treatment or care.
- Improving Access to Psychological Therapies Patient Experience Questionnaire: this self-reported questionnaire gathers participants' experience of the intervention received.

Participant follow-up

Research assistants administered all baseline and post-randomisation questionnaires to participants at each site. All participants were followed up with questionnaires at 4 and 12 months. IAPT Healthy Minds Patient Experience Questionnaire was incorporated at both 4 and 12-month follow-ups, with the Ages and Stage questionnaire included only at 12 months (*Table 2*).

Trial outcome assessments

It has been reported that the validation of clinical assessments should be conducted to meet the needs of diverse population groups to ensure context dependent appropriateness and to determine context specific cut-off scores for use in the study population.[100] It should be noted that despite the growing need to provide clinical care which meets an individual's cultural background, there are considerable barriers to the detection of PND, with many high-income countries, implementing perinatal mental health screening programmes.[99] The delivery of culturally appropriate interventions requires the use of appropriate clinical assessment tools. This is advocated by the World Health Organization (WHO),[101] which recommends the use of screening programmes for conditions which are serious, preventable, and treatable.

Cultural adaptation of clinical assessment tools

The challenge of providing care to vulnerable women from minority backgrounds requires the need for robust research which takes into account the cultural relevance and language needs of this group of women. The present trial was based on the preparatory work in BSA women (ROSHNI-D), with assessment tools being culturally adapted and validated for use in BSA women. The outcome measures and patient information material used in the trial were culturally adapted, and translated using a standardised protocol from the previous work,[54] which

TABLE 2 Schedule of outcome measures

	Visits			
Procedure	**Screening**	**Baseline**	**4 months (end of intervention)**	**12 months**
Informed consent	X			
Demographics		X		
Socioeconomic data		X		
Study assessment				
PHQ-9		X	X	X
HDRS		X	X	X
SCID		X		
GAD-7		X	X	X
EQ-5D-3L		X	X	X
The Parenting Sense of Competence Scale		X	X	X
Social functioning		X	X	X
IAPT Healthy Minds Patient Experience Questionnaire		X	X	X
EPQ		X	X	X

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involved stakeholder input from service users, lay members of the public, and back translation through the use of back-translation techniques.[19,26,102–104]

Sample size

The analysis compared those in the PHP intervention group with women in TAU group using a partially nested design.[105] The sample size calculation and data analysis considered clustering because of this partially nested design. Partial clustering was used, due to the trial including women in the intervention arm receiving the group therapy and benefiting from the group interaction. The methods for the partially nested statistical methods are examined elsewhere.[106] The sample size was 720 participants, consisting of 40 groups of 9 participants and 360 participants in TAU. Giving 90% power to detect a clinically significant difference between a 55% recovery rate in the PHP intervention group and a 40% recovery rate in TAU, with an approximation of intraclass correlation (ICC) for group treatment of 0.05, and 75% follow-up at 4 months, 70% at 12 months and a 5% significance level.

Randomisation and blinding process

The Manchester Clinical Trials Unit randomised participants via a remote telephone randomisation service. The PHP intervention required a group size of 5–9 participants. Therefore, randomisation was stratified by study sites using a block size of 10–18 for allocation, contingent on the size of the site, so that 5–9 participants were randomised to PHP-plus-TAU and 5–9 participants to TAU only. Attempts were made so that the duration between the participant's baseline assessment and randomisation was not longer than 6–8 weeks.

GPs were informed by letter about their patient's participation and treatment allocation. Participants were informed about the allocation via phone call. The TAU participants were informed about the follow-up assessments and points at which to expect contact from the team. The PHP participants were contacted by the allocated facilitators and a 'zero' visit arranged to discuss group attendance and logistics. Due to the nature of the intervention, it was not possible to blind participants, their GPs, or practice health visitors. However, researchers masked to treatment allocation collected the outcome measures.

Ineligible participants

Participants whose assessment outcome using SCID did not indicate PND were followed up with a phone call informing them that they were not eligible for the trial. They were, however, invited to join the local PPIE advisory group for ROSHNI-2.

Health technology being assessed

Treatment as usual

Participants allocated to the TAU group had access to usual GP care. They received primary care management of PND if available and accessed through their GP, which could include routine appointments, referral to IAPT and to other services, and antidepressant prescription. The access to services is described further in *Chapter 6* as part of the health economics evaluation.

Positive Health Programme intervention group

Participants in the intervention group received the PHP, a manual-assisted, culturally adapted group psychological intervention based on CBT principles, designed for BSA women with PND[53] in addition to usual care. The PHP intervention consists of 12 group sessions delivered by two trained bilingual facilitators. PHP facilitators ranged from NHS band 4–6 researchers with a psychology/social sciences/related sciences degree. To develop wider capacity in delivery of culturally adapted therapies, several volunteers were trained from the third sector. During the first 2 months of the intervention, PHP sessions were delivered once a week and thereafter fortnightly for the following 2 months. Each group session lasted approximately 60–90 minutes. Participants were reminded about confidentiality and ground rules at each session, and group members were informed that all disclosures remained confidential, except for matters concerning risk to oneself or others or any other safeguarding issues. Any disclosures that constituted a safety/safeguarding risk was reported using the local NHS trust safeguarding policy and a study specific risk assessment completed and signed off by local PI.

The PHP covered culturally relevant topics, including recognising the pressures on South Asian women, understanding and managing self-esteem, 'keeping up with the Chaudhry's (Jones's)', exercise and looking good, religion and spirituality, relaxation and 'taking time out', culturally appropriate assertiveness and confidence building, breaking social isolation and building social networks, practising CBT techniques and assessing change and developing relapse prevention plans.[26,53] (A detailed table of facilitators and their characteristics including their experience, training, cultural backgrounds, language skills and gender is presented in *Report Supplementary Material 1*. The description of each PHP session is also detailed in *Report Supplementary Material 1* with a summary of key points covered in each session.)

The PHP manual is available in English and the participants' preferred languages – Urdu, Hindi, Bengali, Gujarati and Tamil. All facilitators had a good command of English and many bilingual in the study languages; for each group, facilitators were allocated to match the group's language preferences. A PHP supervisor attended 1–2 of the 12 sessions to assess fidelity. The venues for group sessions were kept neutral to avoid a specific ethnic or religious affiliation.[26] Therefore, PHP was delivered at children's centres and other neutral community venues, as preferred by the participants. Expenses for travel and child-care costs were provided, refreshments and reimbursement of a £10 voucher for each session. The intervention group also had access to TAU.

Training, supervision and competency assurance

The recruited PHP facilitators had variable experiences in the psychological background and were from diverse ethnic backgrounds. Facilitators attended 2 days of the 'train the trainer' course to deliver the PHP intervention. The training consisted of soft skills, including activities in engaging with participants, managing the PHP group discussion, and safeguarding issues. The training focused on mastery of facilitation, behavioural activation, and the antecedents, behaviour, consequences (ABC) model. It involved a didactic and Socratic teaching approach with verbalising the contents of the intervention via presentations, role-plays, and dialogue in discussions. PHP trainers observed facilitators for at least one session, provided practical feedback, and suggested improvement where required. One-day refresher training sessions were also delivered throughout the study.

No standardised tools were utilised for post-training assessment. Instead, the facilitators' performance was evaluated through role-plays conducted during the training sessions. After each role-play, the facilitators received detailed feedback on their performance.

To assess the competency of the facilitators and the fidelity to the intervention, the trainers/supervisors directly observed the facilitators during the group sessions. Prior to the observed session, the participants were informed about the observation. During the observation, the trainer/supervisor quietly positioned themselves at the back of the group, taking notes on their observations and using the session observation form as a checklist for important aspects to be assessed. After the observation, the trainer/supervisor conducted face-to-face supervisions, providing detailed feedback to the facilitators. Each facilitator underwent at least two observations, and in cases where concerns were identified, additional observations were carried out. A 15-item checklist was devised specifically for the purpose of conducting group observations. Each item on the checklist was evaluated using a three-point Likert scale, which ranged from 'not done' to 'done well,' with the additional option of 'not applicable'.

Co-investigator (CO-I) Karina Lovell and PHP trainers formed the supervisory team and provided regular telephone and Skype monthly supervision and ad hoc meetings as needed. These group supervisions provided a platform for facilitators to share their experiences, learn from one another, and discuss challenging cases with their supervisors. Moreover, facilitators were given the option to communicate with their supervisors if they had any concerns regarding any participant.

Trial completion and withdrawal

During the trial period, participants were considered to have withdrawn from the trial on the following basis:

- withdrew consent (participant wished to leave the trial with no further contact or follow-up)
- clinical decision from a health professional for the participant to be withdrawn from the trial
- serious adverse event (persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions or provide ongoing consent).

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Withdrawals

The process of informed consent was considered ongoing for the duration of the study; participants were reminded at each contact point that they had the right to withdraw from the study at any point. With study withdrawal requests, a research assistant explored with the participant to what extent they wished to withdraw from the research and the reason for withdrawal (if they wanted to share). The research assistant logged reasons for withdrawal and whether the withdrawal was from all parts of the study, from the intervention or from the follow-ups. For participants who withdrew from the intervention only, follow-up data continued to be collected. All data collected were retained for all participants until the point of withdrawal unless they explicitly requested their details to be removed, where feasible (until the database was locked).

Clinical risk management protocol

Due to the clinical characteristics of the target population being investigated, there was a risk of suicide or suicidal ideation in this group. The research team adhered to good clinical practice (GCP) in assessing suicide risk during their contact with participants. All participants were registered with the GP and would continue to access care if requested/provided. If acute suicide risk was detected, the protocol for assessing and reporting risk for the study was followed.

Public and patient involvement and engagement

It is also important to note that, in the context of the internal pilot RCT, we continuously asked participating BSA women for their views regarding the study procedures and measures. We introduced several changes as a result of the feedback.

For example, in addition to the face-to-face SCID assessment, the protocol was amended to include the completion of SCID over the phone. This was due to the participant's request to choose the option depending on their circumstances. Either option allowed the participants to decide whether to limit time and travel to the researchers or not to be in the house, avoiding intrusive family members, and maintaining privacy or evading associated stigma.

A key learning point from these events was that BSA women enjoyed contributing to the research, both those who received the intervention and those who did not. Some service users were trained in research methods and attended qualitative research methods training to help with the research study, topic guide and data analysis.

Engagement events

We held numerous community awareness events. These events, 'Chai with ROSHNI-2' and 'Brunch with ROSHNI-2', were successful means of engaging with the BSA community and encouraging significant presence of the BSA women at different study sites. The community events raised awareness about maternal mental health and the ROSHNI-2 study. These included health fairs, school events and community fun days, health seminars and specific seminars to link in with, such as the global women's health seminar to mark 'World Maternal Mental Health week' in which ROSHNI-2 presented. Workshops on depression, particularly PND, were facilitated by third-sector organisations working with the BSA community at the study sites.

Theory of change

We used the workshop to inform the interview topic guides for the qualitative study, particularly on how to address stigma. Theory of change (ToC) workshops were organised to implement various additional strategies during the internal pilot phase which could be carried through to the main trial. The research team utilised the short mid-study closedown period to share the learning with the BSA population across the study sites. The ToC approach provided a robust foundation for impact assessment. The systematic analysis allowed reflection on the trial's contributions to planned changes for the target group. This process allowed the team and stakeholders to understand and report on unexpected/unintended impacts as well as those that were intended. In these workshops, we developed the ToC causal pathway, which visually describes how and why an expected change is likely to occur in a particular context/setting. It describes activities/initiatives (outputs), the sequence of outcomes so that we reach the various milestones that lead to desired goals and articulates the activities and assumptions we have made. The causal pathway ToC provided a detailed and direct understanding of the links between activities that lead to the desired goals. During the proposal stage, we

identified a PPIE member (NM) to provide us with a steer on the project concept, aims and objectives and methodology. Furthermore, NM was included on the application as a named PPIE member. The set-up of the project continued to benefit greatly from NM, and she was able to contribute to the development of participant facing materials. NM attended the first ethics committee meeting and was able to answer questions and ensured the approach, recruitment methodology, and materials were appropriate for the community we wanted to work with whilst also being ethically sound. NM was able to contribute to the researcher training and we found it hugely valuable to have the service user input on appropriate terminology, perceived barriers, understanding how to engage with the community and learning from that lived experience of both postnatal depression and research participation.

A male service user researcher, NMO, joined the team during recruitment. NMO joining the team helped us to engage with men/fathers/husbands and the wider South Asian community. It was important to acknowledge the gender roles within this community, the patriarchal society, and the joint family unit that needed to be engaged. Both NM and NMO were able to provide the team with insight on managing this respectfully when working with families. In particular, those living in multi-generational households where decision-makers are often the husbands or elder family members such as the mother-in-law/father-in-law. NMO and NMs involvement allowed the research team to engage widely in the community, providing a platform to change the narrative of a 'hard-to-reach' community. NMO supported the research team engage with mosques, temples, gurudwaras, schools, nurseries, charities, and community organisations. NMO shared his story as a South Asian male who had experienced psychosis, accessed treatment, tackled cultural barriers and the recovery journey. His story provided powerful insight into the struggles of a South Asian male experiencing mental health difficulties and the stigma that can be worked on through open conversations.

Patient and public involvement and engagement workshops

The research team utilised the study closedown period to share the learning with the BSA population across the study sites. The ToC approach provided a robust foundation for impact assessment. Systematic analysis allowed reflection on the trial's contributions to planned changes for the target group. This process allowed us to understand and report on unexpected/unintended impacts as well as those that were planned. In these workshops we developed the ToC causal pathway, which visually describes how and why an expected change is likely to occur in a certain context/setting. It describes activities/initiatives (outputs), the sequence of outcomes so that we reach the various milestones which lead to desired goals and articulates what activities and assumptions we have made. This provides a visual road map to how we achieve the outcomes. In the workshops, in line with theories of change, we explored various elements including stakeholder engagement, developing a shared vision, and defining short-, medium- and long-term goals. This led to better evaluation and measure of progress and an understanding of impact both planned and unplanned. This exercise provided us with the knowledge about what barriers and challenges were faced in the trial and what assumptions were made in defining the goals. Participants and carers as key stakeholders were direct contributors to any planned and unplanned changes, and their experiences and feedback directly influenced any adjustments that had to be made. The ToC aided in monitoring, reflection on developments, and helped us to see and explain any progress during and after the intervention, where impact had not yet occurred.

The study methodology, recruitment and retention have all been largely influenced by insight from the service users, carers, and wider public. The engagement and involvement allowed us to swiftly move to a remote model of working during the pandemic. We were able to have swift consultations with the PPIE members and wider public to understand if the study could continue with adaptations in methodology and providing a virtual intervention. We also managed to understand the impact of coronavirus disease discovered in 2019 (COVID-19) on this population and maternity outcomes to develop an additional add on study. We held four discussion groups with a total of 25 service users to understand what associated factors should be considered as a result of the pandemic and understand the most appropriate methodology to carry out this add on work. The service users gave us valuable insight into factors that affected their mental health, home schooling, access to care, attitudes to vaccination, and much more. We developed this feedback into a survey study and topic guides for semistructured interviews and discussion groups, which is described further in the add-on report.

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Clinical effectiveness

Primary outcome measure

The primary outcome measure was collected using HDRS[86] at 4 months, a valid and reliable measure of the severity of depression. A score of ≤ 7 on the HDRS indicated remission/recovery from depression.

Data collection schedule

An overview of the time points at which trial data were collected is presented in *Table 2*.

Statistical analysis

We proposed an intention-to-treat analysis. The statistical analysis adopted a logistic random-effects model to calculate the odds ratio (OR) of recovery between treatment arms, with added covariates of study sites, baseline severity of depression scores using PHQ-9 and education (< 8 years, ≥ 8 years). The analysis was used for both the primary outcome measure (end of intervention at 4 months) and the further outcomes (at 12 months). Random intercepts were included for each group in the intervention arm and individuals (i.e. clusters of size 1) in the control arm, and random intercepts for participants to account for repeated measures. For secondary outcomes of continuous nature, we performed a linear random-effects model with aforementioned covariates, plus baseline measures of the outcome variable. For all analyses, a two-sided $p < 0.05$ was statistically significant.

Internal pilot qualitative study

Objectives

1. Explore early barriers/enablers to study participation in order to optimise ongoing trial recruiter training and trial recruitment rates.
2. Identify reasons for continuing or not continuing with the study.

Methods

Recruitment and sampling

We aimed to interview 15 'decliners' (eligible women who declined to participate in the study), 15 trial participants who attended 4 or more PHP sessions and 15 PHP facilitators. A purposive sampling strategy for interviewing was used across the five sites for the trial, and three participants in each category were anticipated to be interviewed from each site, for each category.

Decliners

Researchers invited decliners for an in-depth interview to discuss their reasons for declining to participate in the study. Researchers made contact by telephone or letter (adhering to their stated contact preferences) to invite them to consider participating in an interview. Participants who agreed were sent an information pack, which included a PIS. Potential participants were contacted again after approximately 1 week to confirm whether they would be willing to participate. For those who expressed an interest in participating, a convenient meeting place and time was arranged for those who wished to be interviewed face to face.

Trial participants

Researchers contacted trial participants by telephone or letter (adhering to their stated contact preferences) to invite them to consider participating in an interview. Participants who agreed were sent an information pack, which included a PIS. Potential participants were re-contacted after approximately 1 week to confirm whether they would be willing to participate. A convenient meeting place and time was arranged for those who expressed an interest in a face-to-face interview. A convenient time was agreed upon for those wishing to participate in telephone interviews, and suitable equipment was provided (researchers posted earphones to potential participants for privacy in shared households).

Positive Health Programme facilitators

Group facilitators who delivered at least one complete programme of providing the PHP were invited to participate in the interviews. Researchers contacted PHP facilitators by e-mail to invite them to consider participating in an interview. Participants who agreed were e-mailed an information pack, which included a PIS. Potential participants were contacted again after approximately 1 week to confirm whether they would be willing to participate. A telephone interview was arranged for those who provided consent.

Consent

Prior to the face-to-face interviews, written informed consent to participate in the interview was obtained. For telephone interviews, verbal consent was obtained from participants and audio recorded. Permission was also obtained from trial participants and PHP facilitators to audio record and transcribe the interview verbatim. Interviews were carried out in their preferred language. Where the participants did not speak English as their first language, the interviews were later translated into English for analysis.

Data analysis

Thematic analysis was conducted to analyse the data. This approach was appropriate for analysing data collected through an open-ended procedure, particularly when rich, descriptive data has been gathered. The three researchers [Saadia Aseem (SA), Rebecca Mcphillips (RM) and Jasmin Begum (JB)] met regularly and were responsible for independently carrying out data coding. They received regular supervision from Carolyn Chew-Graham (CCG) and Penny Bee (PB) for the interpretation of the data.

Qualitative study

Objectives

1. To examine the acceptability of the group intervention from the perspective of BSA women and their families.
2. To explore views of the GPs on the group psychological intervention and its impact on practice.
3. To explore perspectives of PHP group facilitators about training and delivery of the intervention.

Methods

Design

Semistructured interviews were conducted with trial participants, withdrawn participants, PHP facilitators and GPs to gather in-depth information on how they perceived the acceptability, engagement, and implementation of PHP intervention. Trial participants shared their views and experiences of receiving PHP, while PHP facilitators shared their experiences and opinions on delivering the PHP intervention. Interviews with GPs explored their experiences of working with BSA women with postnatal depression. Interviews were conducted with trial participants, PHP facilitators and GPs at the end of the intervention period.

Inclusion criteria

- Participants randomised to the intervention arm and withdrew before completing four sessions of the intervention.
- Participants randomised to the intervention arm.
- Participants who attended at least one or more sessions of the PHP.

Positive Health Programme facilitators

- Positive Health Programme facilitator who delivered at least one course of the PHP.
- General practitioners.
- General practitioners whose practices participated in ROSHNI-2.

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Trial participants

For the interviews, trial participants were purposively sampled from the PHP intervention trial database, aiming for variation in terms of geographic location, age and socioeconomic status and ethnicity to enable an in-depth exploration of the perceived impact of the PHP intervention.

Withdrawn trial participants

Trial participants who withdrew were purposively sampled from the trial database to further explore the reasons for discontinuing the PHP trial. Qualitative researchers re-engaged with withdrawn participants by telephone or letter (adhering to their stated contact preferences) to ask if they would consider participating in an interview. Those participants who agreed were sent an information pack, which included a PIS. Potential participants were contacted again after approximately 1 week to confirm whether they would be willing to participate.

Positive Health Programme facilitator participants

Qualitative researchers phoned or e-mailed all GPs and PHP facilitators ask if they would be willing to participate in an interview Interested individuals were e-mailed a PIS with information about the qualitative study.

General practitioner participants

General practitioners involved in the trial were e-mailed to participate in an interview. Interested individuals were e-mailed a PIS with information about the interview study.

Study materials

With input from patient and public involvement (PPI), the research team developed separate sets of topic guides for trial participants, PHP facilitators and GPs during the internal pilot period. These topic guides were further refined after the completion of interviews in the internal pilot to inform the interview topic guides in the main trial.

Data collection

Qualitative researchers conducted interviews at a convenient place and time according to participant preferences, either face-to-face interviews at the participant's home, in neutral settings, such as a children's centres or community centres, or over the telephone. With the consent of participants, all interviews were audio-recorded, transcribed verbatim and anonymised before data analysis. The recruitment period for the qualitative study was from February 2017 to March 2020.

Qualitative data analysis

Initially, the data analysis plan was to utilise a framework analysis. However, the research team employed thematic analysis to discern and highlight significant themes. The themes were subsequently applied to the Theoretical Framework of Acceptability (TFA), specifically focusing on assessing the intervention's acceptability across the seven domains outlined within the framework. This dual methodology facilitated a comprehensive exploration and evaluation of the intervention's acceptability within the study's specific context.

Interviews conducted in English were transcribed verbatim. However, interviews conducted in languages other than English were translated into English and then transcribed verbatim by the qualitative researchers; and analysed by two qualitative researchers. The transcripts were read to identify key themes linked with the qualitative study's aims. An iterative procedure was used to generate new codes, and specified codes were developed as the analysis progressed. After completing the initial coding, the codes were reduced into various themes. The specified key themes focussed on both parts of the study: the support experiences of trial participants and the perceived effectiveness of PHP (trial participants, PHP facilitators and GPs in the intervention arm). After that, transcripts were revisited, and the first qualitative researcher identified developing subthemes within each central theme with the second researcher and through ongoing discussions to agree on, and finalise, themes.

The GP interviews were analysed using only thematic analysis to identify key themes. For the trial participants and the PHP facilitators' interviews, the researchers deductively charted the themes into the seven acceptability domains

in the TFA.[107] TFA was used to analyse the trial participant's and PHP facilitators' data. The TFA is a multiconstruct theoretical framework that can be applied to assess the retrospective acceptability of healthcare interventions from the perspective of intervention recipients. TFA consists of seven component constructs. These seven components were used as a framework for analysis: affective attitude; burden; perceived effectiveness; ethicality; intervention coherence; opportunity costs and self-efficacy.

To enhance reliability, all interview transcripts were coded in NVivo (QSR International, Warrington, UK) by the first qualitative researcher; then, transcripts were coded by the second qualitative researcher. The experiences of participants were charted to summarise and link to the matching themes and subthemes. Both qualitative researchers met to discuss the identified themes, and the discussion continued until a consensus was reached. Descriptive quotes were included to support the validity of the findings.

Remote delivery of the Positive Health Programme intervention during COVID-19 pandemic insight study

During the COVID-19 pandemic period, due to the social distancing rules, the research team sought ethical approval to continue the PHP intervention delivery remotely via video-conferencing platforms to ensure research continuity with participants. This substudy aimed to understand participants' views on the perceived feasibility, acceptability, and sustainability of the face-to-face versus remote delivery of the PHP intervention, and the PHP facilitator's perspectives on the mode of delivery of the PHP.

Design

Semistructured interviews with a subsample of trial participants and PHP facilitators were conducted to understand their perceived feasibility, acceptability, and sustainability of the face-to-face versus remote delivery of the PHP intervention.

Sampling and recruitment

We aimed to sample 15 participants. Participants were sampled purposively from 2 larger study sites – London and North West England. Trial participants were invited to include those who attended both face-to-face and video-conferencing sessions of the PHP intervention from different socioeconomic backgrounds, ages, and native languages. PHP facilitators were invited to include those who delivered both face-to-face and video-conferencing sessions of the PHP intervention.

Analysis

We used thematic analysis to identify key themes. Key themes were charted into the seven acceptability domains in the TFA. The seven components were used as a framework for analysis: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy.

Economic evaluation

The health economic evaluation explored the value for money of the PHP intervention compared to TAU from a health and social care sector costs perspective. For the primary economic analysis (cost–utility analysis), health benefits were quantified in the form of quality-adjusted life-years (QALYs). The cost component included costs of the PHP intervention and participants' use of secondary, primary, and community healthcare resources. The secondary economic analysis (cost-effectiveness analysis) considered HDRS scores as the health outcomes.

Health outcomes and healthcare resource use

Health benefits in the form of QALYs were estimated from responses to EQ-5D-3L questionnaire. The EQ-5D-3L is a generic health-related quality-of-life instrument widely used in clinical trials. This system covers (1) mobility, (2) self-care, (3) usual activities, (4) pain/discomfort and (5) anxiety/depression, each rated on a 3-point Likert scale with higher scores indicating more severe problems. The UK general population value set was used to weigh responses to the five dimensions of EQ-5D.[108,109] Such weighting results in a utility index ranging from 0 (death) to 1 (perfect health). The EQ-5D-3L responses were obtained at baseline, 4- and 12-month follow-ups. QALYs were calculated from time-weighted linear interpolation of the baseline, 4- and 12-month follow-ups utility indices.

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Participants were asked to complete an EPQ at the baseline and at each follow-up. In addition to information on primary and community healthcare use, they were asked to provide details of any inpatient admissions, outpatient appointments, and emergency department attendances and admissions. The primary cost-effectiveness analyses included secondary, primary and community healthcare use besides the costs of the PHP therapy for the intervention arm. Since most of the PHP sessions were covered in 2018 and 2019, unit costs of 2018–9 were used for costing the use of secondary, primary, and community healthcare resources. Unit costs for the primary and community healthcare resources were collated from the Personal Social Services Research Unit (PSSRU).[105] Secondary care use costs were obtained from the NHS England and NHS Improvement National Cost Collection publications for secondary care.

Missing data

Overall mean values (single imputation) of costs and HDRS scores at the baseline were used to impute the missing baseline values of the respective variables.[110] Since the demographic variables are categorical, a missingness indicator was created for each demographic variable. Using logistic regressions, the missingness indicators of the cost components and utility at the 4 and 12 months were regressed on intervention indicator, demographics, baseline costs, baseline utility, and group and study site indicators.

The missing disaggregated costs, utilities and HDRS scores data at the 4 and 12 months were imputed using the predictive mean matching chained method (multiple imputations). The imputation model included baseline values of costs (both primary and secondary), utilities, HDRS scores, demographic indicators, and group and study site indicators. We have included all available information (variables) in the imputation model. The imputation model works like forecasting, so including more and more information always improves the model fit, resulting in better forecasts.[106] Given the amount of missing data, 50 imputed data sets were created.

Statistical analysis

Regression analysis estimated incremental costs and benefits of PHP intervention over and above the TAU. The cost and effect regressions were jointly estimated using the seemingly unrelated regression (SUR) model. The SUR model overcomes any possible correlation between costs and effects. Given the imbalances in the baseline costs and utilities, regression equations included baseline costs and utilities. The regression equations also included age, qualifications, and study site indicators. Other demographics, such as employment and marital statuses, were highly insignificant (p-value of > 0.3), so they were excluded from the regression analysis. Finally, to account for the partially nested nature of the trial, standard errors were clustered at the PHP group-level to account for a possible within-group correlation with control arm participants treated as clusters of size one.[111]

The results are presented in the form of incremental cost, incremental benefits, incremental cost-effectiveness ratios (ICERs), and incremental net monetary benefits (INMBs). Uncertainty was addressed by extracting 5,000 nonparametric bootstrapped samples from the data. The ICERs of the 5,000 bootstrapped samples were plotted on cost-effectiveness plane, which displays the differences in costs and QALYs between PHP and TAU by plotting costs against QALYs. Cost-effectiveness acceptability curve (CEAC) is drawn based on the distribution of the ICERs on the cost-effectiveness plane. CEAC shows the likelihood that PHP is more cost-effective than TAU as a function of the willingness-to-pay (WTP) for one additional QALY. Since the WTP is generally unknown, the indifference point is set at a probability of 0.5 on the vertical axis. Above this point, PHP is more likely to be preferred over TAU in terms of cost-effectiveness.

Sensitivity analysis

Sensitivity analysis introduced two deviations from the missing at random (MAR) assumption that was used to impute the missing data. Additional sensitivity checks included analysis only on the complete case data and excluding secondary care use from the healthcare utilisation.

Chapter 4 Internal pilot study

We conducted an internal pilot study with nested qualitative research. The study duration was 18 months to demonstrate the viability of the full RCT. Progression to the full trial depended on meeting the key objectives and success criteria (stop/go). Although recruitment methods had been established in the earlier completed ROSHNI-D[26] study, the project team needed to evidence similar engagement across multiple study centres and navigate governance procedures across a range of NHS Trusts and academic partners across the country. The internal pilot phase was conducted in line with NIHR guidelines [recruitment rate progression rules for internal pilot studies for Health Technology Assessment (HTA) trials].[112] However, the internal pilot study was faced with challenges, described below.

Ethics and governance

The study start date was set to 1 July 2016 at the point of funding. The study management team experienced delays in the study set-up phase. One reason for this was staff appointments were taking longer than anticipated and a revised ethics system [Health Research Authority (HRA)] was being implemented at the time. The HRA application was submitted on 29 September 2016. A favourable ethics opinion from the North West Greater Manchester South Research Ethics Committee was received on 28 October 2016. The final HRA approval letter was obtained on 6 January 2017. Confirmation of Capacity and Capability at the sponsor Trust was issued on 9 January 2017. This allowed us to start recruitment, but only for the North West centre.

Collaborators agreement

The study had significant delays in finalising the collaboration agreement between the sponsor and other participating NHS Trusts and Higher Education Institute (HEI) organisations. Initially an NIHR standard template model Non-Commercial Agreement (mNCA) was prepared by the sponsor and circulated, this however was not accepted by all HEI organisations, and they requested to enter into a different collaboration agreement. This meant recruitment could not be started at any of the additional study centres. The final collaboration agreement for all centres was signed and a consolidated copy circulated on 10 May 2017. The London study centre was not included in this agreement as they requested to sign a separate standard collaboration agreement. This was signed on 26 May 2017.

Delays in recruitment of research teams

The above delays meant limited study set-up work at the new centres, considering the research staff could not be recruited without the agreements. These delays meant that the additional centres were not able to make a start for 11 months after the actual study start date. The North West centre was an established centre with contacts with primary care, the community centres, and the wider community from the earlier ROSHNI-D study. The lessons learnt from the North West centre were useful for the additional study centres, particularly how best to engage with the different stakeholders. While waiting for the staff to be recruited across the centres, the Local Clinical Research Networks (LCRNs) started to support the identification of primary care recruitment sites. This was challenging as the practices in areas of high South Asian population density were often not research active. The research team from the North West carried out extensive work to engage primary care, community religious, and voluntary sector organisations at each centre to promote the study. Lunch-and-learn sessions were organised at key general practices (6–8) in each centre, attended by one of the senior investigators to provide information about the study and get support from the GP and practice staff to support the recruitment process.

Changes in infrastructure

During this period, there were changes in the LCRNs and across the NHS including the commissioning of health visiting teams which presented significant challenges. Changes in remit and infrastructure were not easy to negotiate compared

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to the anticipated pathways to recruitment. Strong working relationships were established with the LCRNs to fully maximise their support for the trial, such as refining the recruitment process and identifying potential recruitment sites. Though there was a strong LCRN willingness to support the study, there was a lack of bilingual CRN CSOs at any of the centres except Bradford, which made engagement with the BSA population and general practices difficult. The solution suggested by the advisory groups was to facilitate screening from resources within the trial team and additional multilingual sessional staff were recruited to undertake screening activities in the larger London and the North West study centres, which required extra time and resources to be put in place.

Study closedown and restart

Due to the delays described above, 11 months of delivery time was lost from the original project plan. There was a delay of further 2 months (November–December 2017) where recruitment and all trial activity were suspended by the NIHR due to concerns about progress and not meeting internal pilot targets. The monitoring panel made a recommendation to the NIHR to close the study. This was successfully challenged with the support of community partners, and the study was reopened in January 2018. The appeal process involved strong efforts and support from the PIs across all sites and other stakeholders, including Members of Parliament and local councillors who submitted letters of support. The HTA chair reversed the decision and appointed a new independent chair of the Trial Steering Committee (Professor Rod Taylor). Due to the setbacks, an extension for the internal pilot recruitment period was granted until June 2018, and recruitment at all study centres was back in place from February 2018. During the closedown period, the research team engaged with the BSA communities across the study sites to share the learning. Theory of Change workshops were organised to implement the various additional strategies during the pilot phase to inform the main trial.

Results

To accomplish the objectives of the pilot study, data were collected to obtain the number of women screened and their refusals at the time of initial screening for the trial and the baseline assessment. The results highlight that key objectives of the internal pilot were achieved (*Table 3*).

Internal pilot – qualitative study

Introduction

Qualitative methods were embedded in the internal pilot to improve recruitment processes and optimise recruitment, as well as the implementation and engagement of both the intervention and the trial methods. The qualitative study

TABLE 3 Internal pilot – RCT study outcome

	Key objectives of the internal pilot	Outcome
1	Recruitment of sufficient number of general practices to support the trial (4–6 general practices with large BSA population at each site)	• During the pilot period, the team held lunch-and-learn sessions in GP practices within the identified clusters. Service-level agreements were set up with key practices in each site with high-density BSA population
2	The proportion of eligible participants recruited across the five study centres, to examine the feasibility of achieving recruitment targets	• A total of 120 participants were recruited (meeting the minimum target) during the internal pilot (*Table 4* – recruitment rate vs. target rate) • Recruitment was slow in Glasgow. The birth rates were lower than those extrapolated during the funding bid process. In consultation with local site leads, the CI decided to close the Glasgow site and allocated resources to the four study centres actively recruiting
3	Quantify the estimated waiting period from recruitment to randomisation, and initiation of the PHP intervention groups	• The team ensured the waiting period from randomisation to initiation of the PHP was no longer than 6 weeks. The average wait time for IAPT was 12–14 weeks, and during the pilot, we determined that initiating PHP within 8 weeks of randomisation was feasible

TABLE 4 Internal pilot RCT study – recruitment rate vs. target rate

Pilot site	Target total (*N*)	Minimum target (*N*)	Actual (*N*)	Percentage of target (%)
London	72	44	76	50
Yorkshire	72	44	44	29
Glasgow	19	10	0	0
Midlands	36	22	31	21
Total	199	120	151	100

was embedded in the internal pilot to improve recruitment processes and optimise recruitment. The objectives were to understand how to improve the recruitment pathways for the study, retention of participants, and learning for the full trial.

Methods

Recruitment and sampling

We aimed to interview 15 'decliners' (eligible women who declined to participate in the study), 15 trial participants who attended four or more PHP sessions and 15 PHP facilitators. A purposive sampling strategy for interviewing was used across the five sites for the trial, and three participants in each category were anticipated to be interviewed from each site, for each category.

Decliners

Researchers invited decliners for an in-depth interview to discuss their reasons for declining to participate in the study. Researchers made contact by telephone or letter (adhering to their stated contact preferences) to invite them to consider participating in an interview. Participants who agreed were sent an information pack, which included a PIS. Potential participants were contacted again after approximately 1 week to confirm whether they would be willing to participate. For those who expressed an interest in participating, a convenient meeting place and time was arranged for those who wished to be interviewed face to face.

Trial participants

Researchers contacted trial participants by telephone or letter (adhering to their stated contact preferences) to invite them to consider participating in an interview. Participants who agreed were sent an information pack, which included a PIS. Potential participants were contacted again after approximately one week to confirm whether they would be willing to participate. A convenient meeting place and time was arranged for those who expressed an interest in a face-to-face interview. A convenient time was agreed upon for those wishing to participate in telephone interviews, and suitable equipment was provided (researchers posted earphones to potential participants for privacy in shared households).

Positive Health Programme facilitators

Group facilitators who delivered at least one complete programme of providing the PHP were invited to participate in the interviews. Researchers contacted PHP facilitators by e-mail to invite them to consider participating in an interview. Participants who agreed were e-mailed an information pack, which included a PIS. Potential participants were contacted again after approximately one week to confirm whether they would be willing to participate. A telephone interview was arranged for those who provided consent.

Consent

Prior to the face-to-face interviews, written informed consent to participate in the interview was obtained. For telephone interviews, verbal consent was obtained from participants and audio recorded. Permission was also obtained from trial participants and PHP facilitators to audio record and transcribe the interview verbatim. Interviews were carried out in their preferred language. Where the participants did not speak English as their first language, the interviews were later translated into English for analysis.

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Data analysis

Thematic analysis was conducted to analyse the data. This approach was appropriate for analysing data collected through an open-ended procedure, particularly when rich, descriptive data has been gathered. The three researchers (SA, RM and JB) met regularly and were responsible for independently carrying out data coding. They received regular supervision from CCG and PB for the interpretation of the data.

Researchers invited women for semistructured interviews to discuss their reasons for declining to participate in the study. The pilot phase initially aimed to interview 15 decliners, 15 participants who attended four or more PHP sessions, and 15 PHP facilitators. A purposive sampling strategy for interviewing was used across the five sites for the trial, and three participants in each category were invited to be interviewed from each site. However, due to the internal pilot challenges described earlier, including study closedown and restart, the research team could not conduct the target number of interviews with the participants and the facilitators. In total, during the internal pilot a total of seven interviews were conducted, including three trial participants and four PHP facilitators from the North West and London sites. No decliners agreed to be interviewed.

Findings results

Due to the internal pilot challenges described earlier, including study closedown and restart, the research team could not conduct the target number of interviews with the participants and the facilitators. In total, during the internal pilot a total of seven interviews were conducted, including three trial participants and four PHP facilitators from the North West and London sites. No decliners agreed to be interviewed.

Decliners

Study researchers who were in charge of recruiting women for the ROSHNI-2 trial recorded the reasons provided by these women for their decision not to participate in the trial. All study researchers responsible for recruiting women to the ROSHNI-2 documented verbatim reasons that women gave for not wanting to participate in the trial. Out of 397 women who declined to participate in the trial at PHQ-9 screening, 5 women agreed to be interviewed; but then subsequently declined to be interviewed. A total of 46 women declined when approached for SCID assessment, and none agreed to participate in a semistructured interview to explore reasons for declining.

There were various reasons documented given by women who declined to participate in the study. In most cases women gave more than one reason. Most women refused to participate as they were 'not interested in research'; or 'don't have the time' and 'don't' feel the need to take help'. Some women commented that the proposed group intervention did not appeal to them. *Table 5* presents the multiple reasons given by the BSA women. Researchers noted that, in some cases, the decision to participate in the trial appeared to be made for the woman by her husband, a family member, or her mother-in-law.

Optimising recruitment pathways and retention for study

The embedded qualitative study aimed to understand the experiences and acceptability of PHP from the trial participants' and PHP facilitators' viewpoints. The objectives were to understand how to improve the recruitment pathways for the study, retention of participants, and learning for the full trial. Based on the findings of the qualitative pilot study, changes and actions were taken for the main trial, illustrated in *Table 6*.

Discussion

Despite efforts to engage potential participants and collect data, the research team could only conduct limited interviews with trial participants and facilitators. Notably, no decliners (those who declined to participate in the trial) agreed to be interviewed. However, documented notes highlight the reasons for declining participation among eligible BSA women, with collective themes being a lack of interest in research, time constraints and not feeling the need for help. Some women also expressed discomfort in sharing personal information, research mistrust and language difficulties. Family influence, particularly from husbands and mothers-in-law, played a significant role in women's decisions to participate or decline.

TABLE 5 Internal pilot – RCT study: multiples reasons given for declining participation in PHP trial by eligible BSA participants during the internal pilot period

Types of reason	Number of reasons given for declining participation	Percentage (%)
Not interested in research	342	49.1
Reasons unknown	88	12.6
Don't have time/in a rush	138	19.8
Don't want to share personal information	12	1.7
Don't feel the need to obtain help	59	8.5
Not happy for signing consent	4	0.6
Don't trust research	8	1.1
Not able to communicate in the language offered	5	0.7
Not interested in the intervention/PHP	17	2.4
Need to think	6	0.9
Does not feel comfortable in participating in research	18	2.6
Total	697	100

TABLE 6 Internal pilot – learnings to inform main trial

Themes	Key findings from the pilot trial	Changes and actions taken for the main trial
Barriers to participation	Cultural and language barriers	• The research team established contacts with wider stakeholders to consult on the approaches and methods to help refine and finalise the mechanisms for screening and assessments at each study site
	Challenges identified in recruitment was the need to enable potentially eligible BSA women to engage with research staff in a culturally sensitive manner for further study information and screening. This included overcoming language barriers	• The research team held discussions with the centre leads and bilingual CRNs/primary care staff at each site to establish the best methods for recruitment and retention of participants to time and target at each centre • Recognising that the CRN staff would not be able to support screening and recruitment, bilingual sessional staff were appointed to help with recruitment • The team developed detailed site-specific recruitment strategies and Standard Operating Procedures, which were reviewed by the Clinical Trials Unit and the Data Monitoring and Ethics Committee Chair. This included service level agreements with the third sector working with the BSA population
	'One thing which was a bit of hindrance for me was English language. My English is not fluent and sometimes it took longer for me to understand. Similarly, I was not able to explain myself completely because of the language. There should have been an Urdu facilitator in the group as well. I think there were two other women who struggled as well. I was not able to explain myself completely because of the language' (trial participant NW-12-0024)	• Recognising that the CRN staff would not be able to support screening and recruitment, bilingual sessional staff were appointed to help with recruitment

continued

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TABLE 6 Internal pilot – learnings to inform main trial (*continued*)

Themes	Key findings from the pilot trial	Changes and actions taken for the main trial
	Lack of awareness and stigma associated with mental health	• Family-centred recruitment pathways and modification of approaches to study advertising were developed
	'I was a bit reluctant to tell my mom that I have joined the group . . . because she is from the old school of thought and anything about mental health is very stigmatising for her. Also, she will not like that her daughter is suffering from depression nor has any mental health issue' (trial participant NW-13-0030)	We developed how to use a culturally sensitive and confidential family engagement approach. PHP was presented as a problem-solving skills training programme rather than 'therapy', and the word 'stress' was used more rather than depression. The team organised various community engagements such as 'brunch with ROSHNI-2' at all sites. The events were well received in each study site and attended by different community members and postnatal women of South Asian backgrounds
	Participants highlighted that women's lack of trust in health professionals and service providers prevented them from engaging with services	The research team was able to engage key health professionals, such as health visitors and midwives, in all these events
PHP as culturally appropriate	Valued PHP. The group delivery of the PHP was perceived as acceptable and valuable, which helped women to share their experiences with other BSA women, and subsequently which increased their social network support	No changes were required to PHP
Supervision and training	PHP facilitators valued the training sessions they received. Discussed skills they had developed, including listening and communication skills	No significant changes made to training or supervision; however, PHP facilitators were regularly encouraged to contact supervisors as and when needed for queries
'Self explanatory' manual	The usefulness of the 'self-explanatory' PHP manual was perceived as a good guideline for the PHP facilitators	No changes were made to the manual; however, PHP facilitators were given the flexibility to repeat sections of the sessions based on requests made by the women

Key findings and actions were implemented to address these challenges and optimise recruitment pathways for the main trial. These included recognising and addressing cultural and language barriers, developing family-centred recruitment pathways, modifying study advertising and organising community engagement events. The internal pilot phase underscored the importance of tailoring recruitment approaches to the cultural circumstances of BSA women and contending with the stigma and mistrust associated with mental health.

Chapter 5 Results

Sample

A total sample of 732 participants was included in this trial, randomised into two groups: 364 in the TAU group and 368 in the PHP-plus-TAU group (*Figure 3*) . The wait between baseline to randomisation was no more than 4–6 weeks as we aimed to match the NHS Talking Therapies waiting-list time. A total of 15 groups were randomised in London, 21 in North West, 3 in Midlands and 3 in Yorkshire.

During the trial, participants were lost due to following reasons: lost to follow-up (*n* = 189); withdrew on decision of the investigator (*n* = 17); patient request (*n* = 2); withdrawal of consent (*n* = 2); and other (*n* = 1).

Demographic baseline characteristics

Demographic details of study participants are illustrated in *Table 7*.

Age

Mean age of total sample was 31 ± 5.2 years, that is nearly same in both TAU and PHP + TAU group.

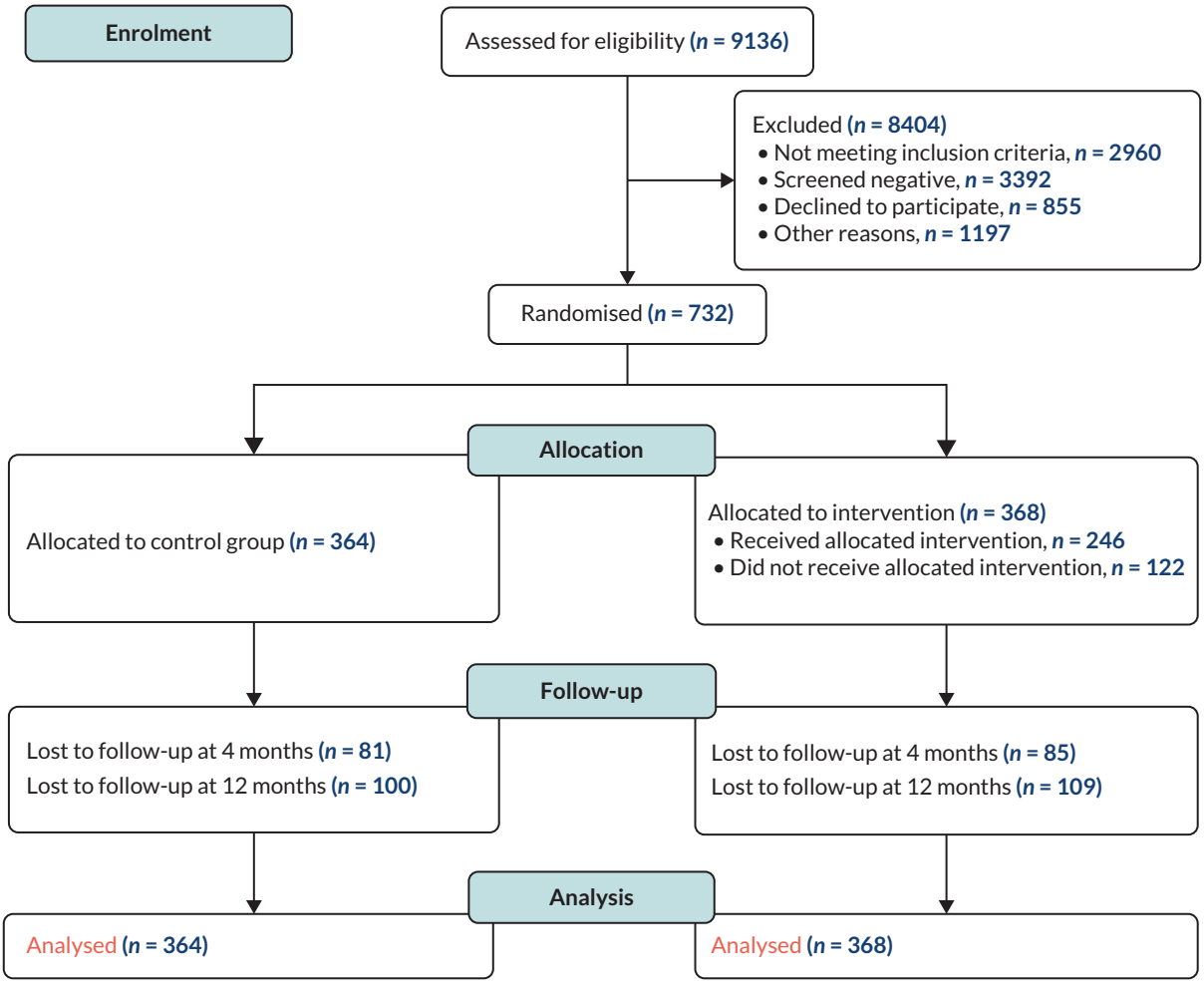

FIGURE 3 ROSHNI-2 study flow design.

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TABLE 7 Baseline characteristics

Baseline characteristics		TAU (*n* = 364)	PHP (*n* = 368)	Sample (*n* = 732)
Age, mean (SD)		31.4 (5.2)	31.3 (5.2)	31.3 (5.2)
Ethnicity, *n* (%)	Indian	85 (24)	91 (24.9)	176 (24.5)
	Bangladeshi	67 (18.9)	60 (16.4)	127 (17.7)
	Pakistani	195 (55.1)	202 (55.3)	397 (55.2)
	Other South Asian	7 (2)	12 (3.3)	19 (2.6)
English speaking, *n* (%)	Yes	327 (92.9)	338 (93.1)	665 (93)
	None	25 (7.1)	25 (6.9)	50 (7)
Religion, *n* (%)	Islam	315 (88.2)	322 (88)	637 (88.1)
	Hindu	28 (7.8)	23 (6.3)	51 (7.1)
	Christian	4 (1.1)	2 (0.5)	6 (0.8)
	Buddhism	0 (0)	3 (0.8)	3 (0.4)
	Sikh	9 (2.5)	16 (4.4)	25 (3.5)
	Other	1 (0.3)	0 (0)	1 (0.1)
Generation, *n* (%)	First generation	215 (60.9)	206 (56.6)	421 (58.7)
	Second generation	103 (29.2)	120 (33)	223 (31.1)
	Third generation	35 (9.9)	38 (10.4)	73 (10.2)
Employment status, *n* (%)	Full-time	44 (12.5)	42 (11.5)	86 (12)
	Part-time	43 (12.2)	56 (15.3)	99 (13.8)
	Unemployed	43 (12.2)	39 (10.7)	82 (11.4)
	Sick	0 (0)	1 (0.3)	1 (0.1)
	Home maker	186 (52.8)	197 (54)	383 (53.4)
	Student	3 (0.9)	2 (0.5)	5 (0.7)
	Other	33 (9.4)	28 (7.7)	61 (8.5)
Highest qualification, *n* (%)	Primary	14 (4)	12 (3.4)	26 (3.7)

Ethnicity

Almost half of the total sample was comprised of individuals of Pakistani ethnicity – 397 (55%), while 176 (25%) were from India, 127 (18%) from Bangladesh and 19 (3%) from other Asian backgrounds. Ethnicity between the TAU and PHP group was distributed equally.

Language

Most participants replied that their preferred language was English, by 316 (43%) participants. Urdu was preferred by 234 (32%), Bengali by 71 (10%), Punjabi by 52 (7%) and Gujarati by 30 (4%) participants. A majority of 665 (93%) participants spoke and understood English and only 50 (7%) lacked confidence in fluent English.

Religion

A total majority of 637 (88%) participants were affiliated to Islam, 51 (7%) were Hindu, 25 (4%) were Sikh, 6 (0.8%) were Christian and 3 (0.4%) were Buddhist. The same pattern was observed in both groups, except Sikh individuals that were slightly more in the PHP group (16 or 4.4%) then in the TAU group (9 or 3%).

Generation
The majority of the overall participants were from first generation (421 or 59%), while the rest of them were from second generation (223 or 31%) and third generation (73 or 10%).

Employment status
Of all participants, 383 (54%) were homemakers, there were 99 (14%) part-time employed, 86 (12%) full-time employed, 82 (11%) unemployed and 5 (0.7%) were students.

Qualification
Participants were asked about their highest qualification. From the total sample, 221 (32%) had first degree, 150 (21%) did A-levels, 119 (17%) had a higher degree, 117 (17%) did GCSEs, 26 (4%) did primary schooling and 68 (10%) had some other type of qualification like a diploma or had done certificate courses. The mean years of education was 13.9 ± 3.6 years.

Marital status
A total of 684 (95%) participants of the overall sample were married or cohabiting, 27 (4%) were divorced, and 11 (2%) were single mums. The mean years of marriage was 6.7 ± 4.8 years. Women were also asked about their previous marital status and were able to respond with either divorced, separated, and widowed as 61 (9%), 29 (5%) and 6 (1%), respectively.

Children status
Participating mothers were asked about the age of their youngest child and the median age in months was 5.7 with interquartile range (IQR) as 3.6 months.

Household members
Participants were also asked about total number of households and we found the median number as 5.1 with IQR as 2. From the overall sample, 495 (69%) were not living with extended family while 220 (31%) were living with extended family.

Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition)
Baseline diagnosis of depression was confirmed by a research assistant who was blind to the allocation status of the participants and administered SCID.[92] The SCID is a semistructured interview and in the context of this study it was conducted as a conversation with the participant and interpreted in the language of their preference. The interview consisted of standardised diagnostic questions arranged in modules corresponding to each DSM-5 Axis I disorder. The depression module was used for this study.

Items
There are nine items as follows:

- Depression mood.
- Work and activities.
- Weight and appetite (increase or decrease).
- Sleep (insomnia or hypersomnia).
- Psychomotor agitation or retardation.
- Loss of energy, tiredness or fatigue.
- Worthlessness or guilt.
- Ability to concentrate.
- Suicide.

Each item has four options as follows:

- Absent or false = 1.
- Sub threshold = 2.

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- Threshold or present or true = 3.
- Inadequate information = ?

Assessment

At least five of the above items (1–9) were coded '3 (present)' and at least one of these item 1 or 2. Expected outcome was from minimum 5 score to maximum 9 score.

Outcome

The SCID score was assessed and the mean score of all participants found was 7.31 ± 1.05. Out of 9 items, minimum 5 was scored by 56 (8%) participants. Similarly, 6 was score by 95 (13%), 7 scored by 215 (29%), 8 scored by 301 (41%) and 9 scored by 65 (9%) participants as shown in *Table 8*.

Outcome measure completeness by study participants

Table 9 shows the completeness of study outcome measures by study participants. For the outcome assessment at both 4 months and 12 months, the denominator refers to the number of participants who attended the outcome assessment but did not complete a particular measure.

Depression

This measure was completed by 727 (99.6%) participants in both study arms at the time of baseline, 360 (99%) in TAU and 367 (99.7%) in PHP group. At the 4-month follow-up, this measure was completed by 282 (98%) participants in TAU and 281 (95%) in PHP group. Similarly, completeness in TAU group is by 262 (72%) and in PHP group by 259 (71%) participants at the 12-month follow-up.

Depression (Patient Health Questionnaire-9)

At baseline this measure was completed by 362 (99.5%) in the TAU and 368 (100.0%) in the PHP group. The TAU group completed this scale at the 4-month follow-up by 281 (98%) and at 12-month by 261 (72%) participants, whereas completeness of this scale in the PHP group by 282 (96%) participants at the 4-month follow-up and by 258 (70%) at the 12-month follow-up.

Anxiety (Generalised Anxiety Disorder-7)

Completeness of this scale at baseline by 356 (98%) in the TAU group and 364 (99%) in the PHP group. This scale was completed at 4-month follow-up by 279 (97%) and 279 (95%) in the TAU and PHP groups respectively, and at 12-month follow-up by 260 (72%) and 256 (69%) in the TAU and PHP groups respectively.

Parenting (Parenting Sense of Competence Scale)

Participants in TAU group completed this scale at baseline, 4 and 12-month follow-ups as A 322 (89%), 248 (86%) and 226 (62%), respectively. While participants in the PHP group completed this scale at baseline, 4- and 12-month follow-ups as 337 (92%), 252 (85%) and 227 (62%), respectively.

TABLE 8 Structured Clinical Interview for DSM-IV scores as scored by study participants

SCID score	Frequency	Percentage (%)
5	56	7.7
6	95	13.0
7	215	29.4
8	301	41.1
9	65	8.9

TABLE 9 Outcome measure completeness by study participants

Clinical scales	Baseline			4 months			12 months		
	TAU *n* (%)	PHP *n* (%)	Overall *N* (%)	TAU *n* (%)	PHP *n* (%)	Overall *N* (%)	TAU *n* (%)	PHP *n* (%)	Overall *N* (%)
Depression (HDRS)	360 (99.4)	367 (99.7)	727 (99.6)	282 (98.3)	281 (95.3)	563 (96.7)	262 (72.2)	259 (70.6)	521 (71.4)
Depression (PHQ-9)	362 (99.5)	368 (100.0)	730 (99.7)	281 (97.9)	282 (95.6)	563 (96.7)	261 (71.9)	258 (70.3)	519 (71.1)
Anxiety (GAD-7)	356 (98.3)	364 (98.9)	720 (98.6)	279 (97.2)	279 (94.6)	558 (95.9)	260 (71.6)	256 (69.8)	516 (70.7)
Parenting (PSCS)	322 (89.0)	337 (91.6)	659 (90.3)	248 (86.4)	252 (85.4)	500 (85.9)	226 (62.3)	227 (61.9)	453 (62.1)
Social functioning	355 (97.5)	360 (97.8)	713 (97.7)	269 (93.7)	269 (91.2)	538 (92.4)	252 (69.4)	249 (67.8)	501 (68.6)
EQ-5D – health today	350 (96.7)	358 (97.3)	708 (97.0)	269 (93.7)	272 (92.2)	541 (93.0)	259 (71.3)	256 (69.8)	515 (70.5)
IAPT satisfaction	–	–	–	261 (90.9)	267 (90.5)	528 (90.7)	253 (69.7)	254 (69.2)	507 (60.5)

PSCS, Parenting Sense of Competence Scale.

Social functioning

This measure was completed at baseline by 355 (96%) participants in the TAU group and 360 (98%) in the PHP group. At 4-month follow-up this measure was completed by 269 (94%) and 269 (91%) participants in the TAU and PHP groups, respectively. Similarly, at 12-month follow-up by 252 (69%) and 249 (68%) participants in the TAU and PHP groups, respectively.

EuroQol-5 Dimensions – health today

This measure at the time of baseline was completed by 350 (97%) participants in the TAU group and 358 (97%) in the PHP group. Participants in the TAU group completed this scale at 4-month follow-up as 269 (94%) and at 12-month follow-up as 259 (72%). Similarly, in the PHP group 272 (92%) participants completed this scale at 4-month follow-up and 256 (70%) at 12-month follow-up.

Improving Access to Psychological Therapies satisfaction

The satisfaction measure was collected at 4- and 12-month follow-ups. Completeness of this scale at 4-month follow-up was by 261 (91%) in the TAU group and 267 (91%) in the PHP group. At 12-month follow-up this measure was completed by 253 (70%) in the TAU group and 254 (69%) in the PHP group.

Outcome measures

Information about outcome measures is presented in *Table 10*.

Depression (Hamilton Depression Rating Scale)

The mean depression score on the HDRS at baseline in the TAU and PHP groups was 18.0 ± 7.29 and 17.6 ± 7.27, respectively. This score reduced more in the PHP group at both 4- and 12-month follow-ups to 9.0 ± 7.07 and 8.6 ± 6.75, respectively. The HDRS score reduced in the TAU group at 4- and 12-month follow-ups to 11.0 ± 7.85 and 9.4 ± 8.43, respectively.

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TABLE 10 Study participants outcome measures scoring by time point

	Baseline			4 Months			12 Months		
Clinical scales	TAU mean (SD)	PHP mean (SD)	Overall mean (SD)	TAU mean (SD)	PHP mean (SD)	Overall mean (SD)	TAU mean (SD)	PHP mean (SD)	Overall mean (SD)
Depression (HDRS)	18.0 (7.28)	17.6 (7.27)	17.8 (7.28)	11.0 (7.83)	9.0 (7.07)	10.0 (7.52)	9.4 (8.41)	8.6 (6.75)	9.0 (7.62)
Depression (PHQ-9)	15.9 (4.21)	15.2 (3.93)	15.5 (4.08)	9.1 (6.34)	7.2 (5.80)	8.1 (6.12)	7.6 (6.81)	6.8 (5.55)	7.2 (6.22)
Anxiety (GAD-7)	11.6 (5.62)	11.6 (5.87)	11.6 (5.73)	7.4 (5.71)	6.1 (5.66)	6.7 (5.72)	6.4 (6.26)	6.0 (5.51)	6.2 (5.90)
Parental sense comp	62.4 (10.92)	63.0 (12.01)	62.6 (11.49)	67.2 (10.77)	69.1 (12.25)	68.2 (11.59)	67.4 (12.61)	69.9 (12.32)	68.7 (12.59)
Social functioning	13.0 (9.67)	12.9 (9.85)	13.0 (9.74)	8.0 (8.75)	6.6 (7.76)	7.3 (8.27)	6.7 (8.77)	6.0 (7.98)	6.4 (8.38)
EQ-5D – health today	55.3 (20.44	55.4 (19.80)	55.4 (20.13)	64.3 (21.55)	66.2 (21.60)	65.2 (21.55)	65.9 (21.71)	68.1 (21.10)	66.8 (21.44)
IAPT satisfaction	–	–	–	3.3 (0.85)	3.6 (0.68)	3.5 (0.78)	3.6 (0.69)	3.7 (0.65)	3.6 (0.67)

Note
The primary outcome is recovery from PND, measured with the HDRS, with lower scores indicating higher recovery. Depression was measured with the PHQ-9, with lower scores indicating fewer depressions. Anxiety was measured with the GAD-7, with lower scores indicating less anxiety. The PSCS measures how competent the patient feels in their parenting ability, with higher scores indicating higher feelings of competence. The social functioning scale measures social dysfunction, with higher scores indicating higher levels of social dysfunction. The EQ-5D is a rating of the patient's health state on the day, higher scores indicate higher health. The IAPT satisfaction scale is a measure of satisfaction of patient experience and higher scores indicate higher satisfaction.

Depression (Patient Health Questionnaire-9)

The mean depression score at baseline on PHQ-9 recoded as 15.9 ± 4.22 in the TAU group and 15.2 ± 3.92 in the PHP group. This score reduced in both groups but more in the PHP group at 4- and 12-month follow-ups. In the TAU group it reduced to 9.1 ± 6.34 at 4-month follow-up and 7.6 ± 6.81 at 12-month follow-up. Similarly, in the PHP group it reduced to 7.2 ± 5.80 at 4-month follow-up and 6.8 ± 5.55 at 12-month follow-up.

Anxiety (Generalised Anxiety Disorder-7)

Both the TAU and PHP groups showed the same mean anxiety score as 11.6 ± 5.6 at baseline. This score reduced to 7.4 ± 5.71 in the TAU group and 6.1 ± 5.66 in the PHP group at 4-month follow-up and to 6.4 ± 6.26 in the TAU group and 6.0 ± 5.51 in PHP group at 12-month follow-up.

The Parenting Sense of Competence Scale

In the TAU group, the mean parenting sense of competence scale (PSCS) score was 62.4 ± 10.89 and 63.0 ± 12.01 in the PHP group at baseline. At 4-month follow-up this score raised to 67.2 ± 10.77 in the TAU group and 69.1 ± 12.25 in the PHP group. A slight increase was observed at 12-month follow-up as 67.4 ± 12.61 in the TAU group and 69.9 ± 12.32 in the PHP group.

Social functioning

At baseline, the mean score for social functioning was 13.0 ± 9.67 and 12.9 ± 9.85 in the TAU and PHP groups, respectively. In the TAU group this score reduced to 8.0 ± 8.75 at 4-month follow-up and to 6.7 ± 8.77 at 12-month follow-up. Similarly, in the PHP group this score reduced to 6.6 ± 7.76 at 4-month follow-up and to 6.1 ± 7.98 at 12-month follow-up.

EuroQol-5 Dimensions – health today

The mean EQ-5D visual analogue score at baseline was 55.3 ± 20.44 in the TAU group and 55.4 ± 19.80 in the PHP group. This score raised to 64.3 ± 21.55 in the TAU group and to 66.2 ± 21.60 in the PHP group at 4-month follow-up. At 12-month follow-up, the score in the TAU group was 65.9 ± 21.71 and in the PHP group was 68.1 ± 21.10.

Improving Access to Psychological Therapies satisfaction

Satisfaction of study participants was assessed at 4- and 12-month follow-ups. The IAPT mean satisfaction score at 4-month follow-up was 3.3 ± 0.83 in the TAU group and 3.6 ± 0.71 in the PHP group. Similarly, the mean score at 12-month follow-up in the TAU and PHP groups was 3.6 ± 0.69 and 3.7 ± 0.65, respectively.

Mobility

At baseline, some problems were reported by 73 (21%) participants in the TAU group and 80 (22%) participants in the PHP group. The number reduced to 47 (17%) in the TAU group and 37 (13%) in the PHP group at the 4-month follow-up. At the 12-month follow-up, 37 (14%) participants in the TAU group and 28 (11%) in the PHP group reported some mobility problems.

Self-care

Some self-care problems were reported by 100 (28%) participants in both the TAU and PHP groups at baseline. The condition improved at the 4-month follow-up, with 53 (19%) participants in the TAU group and 34 (12%) in the PHP group reporting some self-care problems. Further improvement was observed at the 12-month follow-up, with 32 (12%) in the TAU group and 24 (9%) in the PHP group reporting some self-care problems.

Usual activities

Some problems with usual activities were reported by 161 (45%) participants in the TAU group and 170 (47%) participants in the PHP group at baseline. At the 4-month follow-up, it was found that 76 (27%) participants in the TAU group and 51 (18%) participants in the PHP group had some problems with usual activities. Further improvement was observed at the 12-month follow-up, with 57 (22%) participants in the TAU group and 33 (13%) participants in the PHP group reporting some problems.

Pain/discomfort

Extreme pain was reported by 44 (12%) participants in the TAU group at the baseline. Only 18 (7%) TAU group participants reported pain at 4-month follow-up and 19 (7%) participants at the 12-month follow-up. In the PHP group, 36 (10%) had extreme pain at the baseline, 22 (8%) at 4-month follow-up and 12 (5%) at 12-month follow-up.

Anxiety/depression

At baseline, 58 (16%) participants in both groups reported extreme depression. This proportion improved at 4-month follow-up, with extreme depression reported by 23 (8%) participants in the TAU group and 18 (7%) participants in the PHP group. However, at 12-month follow-up, there was an increase in the proportion of participants reporting extreme depression. *Table 11* presents scores on the EuroQoL measure.

TABLE 11 EuroQol-5 Dimensions questionnaire

	Baseline			4 months			12 months		
Clinical scales	**TAU *n* (%)**	**PHP *n* (%)**	**Overall *N* (%)**	**TAU *n* (%)**	**PHP *n* (%)**	**Overall *N* (%)**	**TAU *n* (%)**	**PHP *n* (%)**	**Overall *N* (%)**
Mobility									
No problems	280 (78.7)	283 (77.5)	563 (78.1)	229 (82.4)	241 (86.4)	470 (84.4)	223 (85.4)	228 (89.1)	451 (87.2)
Some problems	73 (20.5)	80 (21.9)	153 (21.2)	47 (16.9)	37 (13.3)	84 (15.1)	37 (14.2)	28 (10.9)	65 (12.6)

continued

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TABLE 11 EuroQol-5 Dimensions questionnaire (*continued*)

Clinical scales	Baseline			4 months			12 months		
	TAU *n* (%)	PHP *n* (%)	Overall *N* (%)	TAU *n* (%)	PHP *n* (%)	Overall *N* (%)	TAU *n* (%)	PHP *n* (%)	Overall *N* (%)
Confined to bed	3 (0.8)	2 (0.5)	5 (0.7)	2 (0.7)	1 (0.4)	3 (0.5)	1 (0.4)	0 (0.0)	1 (0.2)
Self-care									
No problems	251 (70.5)	258 (70.7)	509 (70.6)	221 (79.5)	241 (86.4)	462 (82.9)	227 (87.0)	232 (90.6)	459 (88.8)
Some problems	100 (28.1)	100 (27.4)	200 (27.7)	53 (19.1)	34 (12.2)	87 (15.6)	32 (12.3)	24 (9.4)	56 (10.8)
Unable to wash self	5 (1.4)	7 (1.9)	12 (1.7)	4 (1.4)	4 (1.4)	8 (1.4)	2 (0.8)	0 (0.0)	2 (0.4)
Usual activities									
No problems	179 (50.3)	177 (48.5)	356 (49.4)	197 (70.9)	224 (80.3)	421 (75.6)	201 (77.0)	222 (86.7)	423 (81.8)
Some problems	161 (45.2)	170 (46.6)	331 (45.9)	76 (27.3)	51 (18.3)	127 (22.8)	57 (21.8)	33 (12.9)	90 (17.4)
Unable to perform	16 (4.5)	18 (4.9)	34 (4.7)	5 (1.8)	4 (1.4)	9 (1.6)	3 (1.2)	1 (0.4)	4 (0.8)
Pain/discomfort									
None	110 (30.9)	119 (32.6)	229 (31.8)	139 (49.8)	155 (55.6)	294 (52.7)	165 (63.2)	156 (60.9)	321 (62.1)
Moderate	202 (56.7)	210 (57.5)	412 (57.1)	122 (43.8)	102 (36.6)	224 (40.1)	77 (29.5)	88 (34.4)	165 (31.9)
Extreme	44 (12.4)	36 (9.9)	80 (11.1)	18 (6.5)	22 (7.9)	40 (7.2)	19 (7.3)	12 (4.7)	31 (6.0)
Anxiety/depression									
None	66 (18.5)	92 (25.2)	158 (21.9)	138 (49.8)	156 (55.9)	294 (52.9)	146 (55.9)	146 (57.0)	292 (56.5)
Moderate	232 (65.2)	215 (58.9)	447 (62.0)	116 (41.9)	105 (37.6)	221 (39.7)	89 (34.1)	88 (34.4)	177 (34.2)
Extreme	58 (16.3)	58 (15.9)	116 (16.1)	23 (8.3)	18 (6.5)	41 (7.4)	26 (10.0)	22 (8.6)	48 (9.3)

Note
This table shows the proportion in each category for each domain of the EuroQol questionnaire.

Health service utilisation by study participants during study period

Study participants were asked about health services utilisation at three time points (baseline, 4- and 12-month) during the study. Details of various services utilisation are presented in *Table 12*.

Use of inpatient services

Inpatient services were utilised by 38 (11%) in the TAU group and 37 (11%) in the PHP group at baseline. Similarly, utilisation at 4-month follow-up was by 12 (4%) in the TAU group and by 11 (4%) in the PHP group. At 12-month follow-up it was by 9 (4%) in the TAU group and by 7 (3%) in the PHP group. The mean inpatient days spent by study participants at baseline in the TAU and PHP groups were 2.5 ± 1.76 and 6.7 ± 7.43, respectively; at 4-month follow-up were 1.4 ± 1.19 and 1.7 ± 1.25; and at 12-month were 3.0 ± 2.08 and 2.0 ± 1.41, respectively.

TABLE 12 Service utilisation by study participants during study period

	Baseline			4 months			12 months		
Description	TAU	PHP	Overall	TAU	PHP	Overall	TAU	PHP	Overall
Use of inpatient services – Yes *n* (%)	38 (11.4)	37 (10.9)	75 (11.2)	12 (4.3)	11 (4.0)	23 (4.2)	9 (3.5)	7 (2.7)	16 (3.1)
Impatient days – mean (SD)	2.5 (1.76)	6.7 (7.43)	4.6 (5.76)	1.4 (1.19)	1.7 (1.25)	1.5 (1.19)	3.0 (2.08)	2.0 (1.41)	2.5 (1.79)
Use of outpatient services – Yes *n* (%)	22 (6.6)	22 (6.5)	44 (6.6)	31 (11.2)	26 (9.4)	57 (10.3)	19 (7.3)	30 (11.8)	49 (9.5)
Number of visits – mean (SD)	2.0 (1.24)	1.6 (1.12)	1.8 (1.18)	1.9 (1.19)	3.6 (5.12)	2.7 (3.64)	2.1 (1.64)	1.8 (1.29)	1.9 (1.41)
Within last month – mean (SD)	1.6 (1.70)	0.9 (1.04)	1.3 (1.43)	1.0 (0.96)	2.0 (3.80)	1.4 (2.66)	1.8 (1.68)	1.2 (1.41)	1.4 (1.52)
Hospital visits – Yes *n* (%)	11 (3.3)	11 (3.3)	22 (3.3)	9 (3.3)	16 (5.8)	25 (4.5)	6 (2.3)	12 (4.7)	18 (3.5)
Number of visits – mean (SD)	1.8 (0.97)	1.4 (1.51)	1.6 (1.23)	2.0 (2.51)	1.5 (0.97)	1.7 (1.68)	2.0 (1.15)	2.2 (1.30)	2.2 (1.21)
Within last month – mean (SD)	0.8 (0.75)	0.7 (0.52)	0.8 (0.62)	1.0 (1.10)	0.8 (0.67)	0.9 (0.83)	1.0 (1.73)	1.2 (0.84)	1.1 (1.13)
A&E visits – Yes *n* (%)	16 (4.8)	14 (4.1)	30 (4.5)	15 (5.4)	16 (5.8)	31 (5.6)	8 (3.1)	8 (3.1)	16 (3.1)
Number of visits – mean (SD)	0.9 (1.09)	0.8 (0.93)	0.8 (1.00)	0.6 (1.27)	0.7 (1.17)	0.6 (1.21)	0.5 (0.74)	1.0 (1.76)	0.7 (1.33)
Within last month – mean (SD)	0.3 (0.46)	0.3 (0.56)	0.3 (0.51)	0.2 (0.42)	0.3 (0.74)	0.2 (0.60)	0.3 (0.44)	0.5 (1.01)	0.4 (0.75)
A&E inpatient visits – Yes *n* (%)	4 (1.2)	5 (1.5)	9 (1.4)	3 (1.1)	5 (1.9)	8 (1.5)	3 (1.2)	4 (1.6)	7 (1.4)
Number of visits – mean (SD)	1.0 (0.00)	1.7 (1.15)	1.4 (0.89)	1.0 (0.00)	2.7 (2.08)	2.0 (1.73)	1.0 (0.0)	1.5 (0.71)	1.3 (0.58)
Within last month – mean (SD)	0 (0)	0.7 (0.58)	0.7 (0.58)	0.5 (0.71)	0.0 (0.00)	0.3 (0.50)	1.0 (0.0)	1.0 (0.0)	1.0 (0.00)
Use of GP services – Yes *n* (%)	175 (52.6)	168 (50.3)	343 (51.4)	128 (46.2)	136 (49.1)	264 (47.7)	94 (36.4)	93 (36.6)	187 (36.5)
Number GP visits – mean (SD)	2.0 (1.70)	2.2 (1.61)	2.1 (1.66)	2.2 (1.78)	2.1 (1.72)	2.1 (1.75)	1.5 (1.33)	1.9 (1.76)	1.7 (1.56)
Within last month – mean (SD)	1.1 (1.01)	1.3 (1.14)	1.2 (1.08)	1.0 (1.09)	1.0 (1.01)	1.0 (1.05)	1.0 (1.22)	1.1 (1.27)	1.1 (1.24)
Number of home visits – mean (SD)	0.3 (0.59)	0.7 (1.37)	0.6 (1.13)	0.1 (0.27)	0.0 (0.00)	0.0 (0.19)	0.1 (0.50)	0.1 (0.28)	0.1 (0.41)
Within last month – mean (SD)	0.1 (0.32)	0.0 (0.20)	0.1 (0.25)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Number of nurse surgery visit – mean (SD)	0.6 (1.25)	0.6 (1.21)	0.6 (1.21)	0.2 (0.49)	0.2 (0.58)	0.2 (0.54)	0.3 (0.75)	0.4 (0.50)	0.4 (0.63)
Within last month – mean (SD)	0.4 (0.70)	0.0 (0.21)	0.2 (0.50)	0.1 (0.26)	0.0 (0.17)	0.0 (0.22)	0.1 (0.37)	0.1 (0.37)	0.1 (0.36)
Number of nurse home visits – mean (SD)	0.4 (0.89)	0.5 (1.71)	0.5 (1.38)	0.1 (0.38)	0.7 (3.49)	0.4 (2.60)	0.1 (0.33)	0.5 (1.10)	0.3 (0.81)

continued

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TABLE 12 Service utilisation by study participants during study period (*continued*)

Description	Baseline			4 months			12 months		
	TAU	PHP	Overall	TAU	PHP	Overall	TAU	PHP	Overall
Within last month – mean (SD)	0.1 (0.34)	0.2 (0.71)	0.2 (0.57)	0.0 (0.00)	0.0 (0.17)	0.0 (0.13)	0.1 (0.25)	0.3 (0.45)	0.2 (0.37)
Number of walk-in visits – mean (SD)	0.3 (0.82)	0.4 (0.99)	0.4 (0.91)	0.9 (2.28)	0.5 (0.93)	0.7 (1.74)	0.6 (0.64)	0.6 (0.96)	0.6 (0.78)
Within last month – mean (SD)	0.7 (1.62)	0.2 (0.54)	0.4 (1.14)	0.3 (0.75)	0.2 (0.59)	0.3 (0.67)	0.4 (0.59)	0.3 (0.46)	0.3 (0.53)
Number of counsellor visits – mean (SD)	1.6 (2.94)	1.2 (2.92)	1.4 (2.90)	1.1 (4.49)	0.5 (1.69)	0.8 (3.30)	1.1 (3.99)	1.0 (2.35)	1.0 (3.18)
Within last month – mean (SD)	0.7 (1.17)	0.5 (1.12)	0.6 (1.14)	0.5 (1.61)	0.2 (0.58)	0.3 (1.18)	0.1 (0.50)	0.2 (0.56)	0.2 (0.53)
Number of community-based mental health service visits – mean (SD)	0.0 (0.74)	0.0 (0.20)	0.0 (0.54)	0.0 (0.19)	0.0 (0.23)	0.0 (0.21)	0.0 (0.37)	0.0 (0.05)	0.0 (0.26)
Within last month – mean (SD)	0.0 (0.32)	0.0 (0.05)	0.0 (0.23)	0.0 (0.06)	0.0 (0.00)	0.0 (0.04)	0.0 (0.16)	0.0 (0.00)	0.0 (0.11)
Number of community-based mental health service visits – mean (SD)	0.0 (0.74)	0.0 (0.20)	0.0 (0.54)	0.0 (0.19)	0.0 (0.23)	0.0 (0.21)	0.0 (0.37)	0.0 (0.05)	0.0 (0.26)
Within last month – mean (SD)	0.0 (0.32)	0.0 (0.05)	0.0 (0.23)	0.0 (0.06)	0.0 (0.00)	0.0 (0.04)	0.0 (0.16)	0.0 (0.00)	0.0 (0.11)

SD, standard deviation.

Use of outpatient services

Outpatient services at the time of baseline were utilised by 22 (7%) participants in the TAU group and 22 (7%) in the PHP group. At 4-month follow-up services were utilised by 31 (11%) in the TAU group and by 26 (9%) in the PHP group. Similarly, 19 (7%) in the TAU group and 30 (12%) in the PHP group utilised this service at 12-month follow-up. Details of the mean number of visits are illustrated in *Table 12*.

Hospital visits

Hospitals visits at baseline were done by 11 (3%) each in both the TAU and PHP groups. Frequency of visits by participants in the TAU and PHP groups at 4-month follow-up was 9 (3%) and 16 (6%), respectively, while at 12-month follow-up was 6 (2%) and 12 (5%), respectively. *Table 12* describes the mean number of days this service was utilised at different time points in study.

Accident and emergency visits

When participants were asked about accident and emergency (A&E) visits at the time of baseline, 16 (5%) in the TAU group and 14 (4%) in the PHP group were affirmative. At 4-month follow-up, 15 (5%) participants in the TAU group and 16 (6%) in the PHP group did the A&E visit. Likewise, at 12-month follow-up, 8 (3%) participants in the TAU group and 8 (3%) in the PHP group did the A&E visit. Further details about the mean number of visits are provided in *Table 12*.

Accident and emergency inpatient visits

Participants also have inpatient visit, 4 (1%) in the TAU group and 5 (1%) in the PHP group at baseline. Of those in the TAU group, 3 (1%) said yes and in the PHP group and 5 (2%) said yes at 4-month follow-up. At 12-month follow-up, 3 (1%) participants in the TAU group and 4 (2%) in the PHP group said yes. Details of the mean number of visits are available in *Table 12*.

Use of general practitioner services

The most utilised service by study participants is a GP service. For the TAU group, participants who visited a GP at baseline were 175 (53%), at 4-month follow-up were 128 (46%) and at 12-month follow-up were 94 (36%). Similarly, among the PHP group, 168 (50%) participants visited a GP at baseline, 136 (49%) at 4-month follow-up and 93 (37%) at 12-month follow-up. The mean number of visits by participants are briefed in *Table 12*.

Outcome classification

Primary outcome

The primary outcome was recovery from PND. Patients were considered recovered if they had a HRDS score of 7 or less. If they scored above 7, they were considered to still be depressed. At 4 months, almost half of patients in the treatment (PHP) group were recovered 138 (49%) whereas 105 (37%) were recovered in the control (TAU) group. By 12 months, the control (TAU) and treatment (PHP) group had over over 50% recovery as 140 (54%) and 141 (54%), respectively (*Table 13*).

Secondary outcome

One of the secondary outcomes was regarding whether we observed a treatment response on the HRDS measure. A treatment response was considered a reduction of 50% or more from baseline score on the HRDS. In the treatment (PHP) group, we observed 158 (56 %) of participants experiencing a treatment response and 112 (40%) of the control (TAU) group experiencing a treatment response, at 4 months. At 12 months, 158 (61%) of the treatment (PHP) group had a treatment response and 151 (58%) of the control (TAU) group had a treatment response.

Depression and anxiety scores using the PHQ-9 and GAD-7 can be further categorised into groups depending on severity of symptoms. *Table 14* shows the proportion in each classification, at each time point, within the treatment groups and overall. On PHQ-9, severity of symptoms was classified as minimal symptoms, minor depression, major depression and major depression severe. Major depression was reduced from baseline as 129 (36%) to 36 (13%) at 4-month follow-up and 34 (13%) at 12-month follow-up in the TAU group. Similarly, in the PHP group major depression reduced from baseline as 119 (32%) to 30 (11%) at 4-month follow-up and 26 (10%) at 12-month follow-up.

Primary outcome analysis – recovery

We used a logistic regression, partially nested, random-effects model to appraise the OR of recovery in connection with treatment clusters. We adjusted for baseline depression, parity and education, and included a random intercept for therapy group. At 4 months, we have seen a significant difference in the odds of recovering for those in the treatment group, who were almost twice as likely to recover at 4 months than Group A (OR 1.97, 95% CI 1.26 to 3.10). At 12 months, we no longer observe a significant difference in the odds of recovering from postnatal depression (*Table 15*).

Table 16 shows the differences in continuous outcomes between groups. For depression, measured by the PHQ-9 score, we see that the treatment group has a significantly lower depression score than the group at 4 months (β = 2.05, 95% CI −3.18 to −0.92). There was no significant difference observed at 12 months. At 4 months, the treatment group had significantly lower anxiety compared to the control group (β = 1.45, 95% CI −2.66 to −0.25). At 12 months, we do not see a significant difference in anxiety between groups.

TABLE 13 Outcome classification – primary outcome

Clinical scales	Baseline			4 months			12 months		
	TAU	PHP	Overall	TAU	PHP	Overall	TAU	PHP	Overall
	n (%)	*n* (%)	*N* (%)	*n* (%)	*n* (%)	*N* (%)	*n* (%)	*n* (%)	*N* (%)
Depressed	336 (94.9)	338 (93.1)	674 (94.0)	176 (62.6)	143 (50.9)	319 (56.8)	121 (46.4)	118 (45.6)	239 (46.0)
Recovered	18 (5.1)	25 (6.9)	43 (6.0)	105 (37.4)	138 (49.1)	243 (43.2)	140 (54.4)	141 (54.4)	281 (54.0)

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TABLE 14 Outcome classifications – secondary outcome

Outcome		Baseline			4 months			12 months		
		TAU, *n* (%)	PHP, *n* (%)	Overall, *N* (%)	TAU, *n* (%)	PHP, *n* (%)	Overall, *N* (%)	TAU, *n* (%)	PHP, *n* (%)	Overall, *N* (%)
Reduction in HRDS	< 50% reduction	–	–	–	167 (59.9)	123 (43.8)	290 (51.8)	109 (41.9)	101 (39.0)	210 (40.5)
	50% or more reduction	–	–	–	112 (40.1)	158 (56.2)	270 (48.2)	151 (58.1)	158 (61.0)	2309 (59.5)
PHQ classification	Minimal symptoms	0 (0.0)	1 (0.3)	1 (0.1)	159 (56.8)	200 (70.9)	359 (63.9)	170 (67.5)	183 (72.3)	353 (69.9)
	Minor depression	150 (41.6)	183 (49.7)	333 (45.7)	63 (22.5)	43 (15.3)	106 (18.9)	31 (11.9)	40 (15.5)	71 (13.7)
	Major depression	129 (35.7)	119 (32.3)	248 (34.0)	36 (12.9)	30 (10.6)	66 (11.7)	34 (13.1)	26 (10.1)	60 (11.6)
	Major depression severe	82 (22.7)	65 (17.7)	147 (20.2)	22 (7.9)	9 (3.2)	31 (5.5)	20 (7.7)	5 (1.9)	25 (4.8)
GAD classification	Minimal symptoms	38 (10.7)	46 (12.6)	84 (11.7)	10.7 (38.6)	138 (49.5)	245 (44.1)	132 (51.0)	133 (52.0)	264 (52.0)
	Mild anxiety	96 (27.0)	94 (25.8)	190 (26.4)	72 (26.0)	72 (25.8)	144 (25.9)	57 (22.0)	63 (24.6)	120 (23.3)
	Moderate anxiety	113 (31.7)	102 (28.0)	215 (29.9)	64 (23.1)	38 (13.6)	102 (18.4)	35 (13.5)	31 (12.1)	66 (12.8)
	Severe anxiety	109 (30.6)	122 (33.5)	231 (32.1)	34 (12.3)	31 (11.1)	65 (11.7)	33 (13.5)	29 (11.3)	64 (12.4)

In terms of parenting competence (PSCS), there was no significant difference in parenting sense of competence scores at 4 months between groups. However, at 12 months, the control group had a higher score, on average by 3.32 points (95% CI 1.10 to 5.54), indicating significantly higher sense of competence than the control group. There was no significant difference in social functioning between groups at 4 or 12 months. Regarding the patient's health state on the day, there was no significant difference in scores between groups at each time point.

Secondary outcome analysis – recovery

We used a logistic regression model to estimate the association between the intervention and whether a women had a response to treatment. A treatment response was defined as a decrease in HRDS score by 50% or more from baseline. We adjusted for parity and education and included a random intercept for therapy group. At 4 months, we saw that the treatment group were over twice as likely to experience a treatment response than the TAU group. This was a significant difference in odds (OR 2.49, 95% CI 1.38 to 4.52). However, at 12 months, we did not observe a significant difference in the proportion of patients experiencing a treatment response between groups (OR 1.07, 95% CI 0.59 to 1.95) (*Table 17*).

TABLE 15 Primary outcome analysis – recovery from postnatal depression

Outcome	TAU, *n* (%)	PHP, *n* (%)	OR (SE); *p*-value (95% CI)
Baseline	19 (5.3)	25 (6.8)	–
4 months	105 (37.4)	138 (49.1)	1.97 (0.45); $p = 0.003$ (1.26 to 3.10)
12 months	140 (53.6)	141 (54.4)	1.02 (0.27); $p = 0{,}80$ (0.62 to 1.66)

TABLE 16 Secondary outcomes

	TAU; Unadjusted mean (SD)	PHP; Unadjusted mean (SD)	Adjusted difference[a] (SE); *p*-value (95% CI)	Cohen's *d* (95% CI)
PHQ				
Baseline	15.85 (4.21)	15.21 (3.93)	–	
4 months	9.09 (6.34)	7.22 (5.80)	−2.05 (0.58); *p* <0.0001 (−3.18 to −0.92)	
12 months	7.60 (6.81)	6.77 (5.55)	−0.89 (0.59); *p* = 0.13 (−2.05 to 0.27)	
GAD				
Baseline	11.60 (5.62)	11.56 (5.87)	–	
4 months	7.37 (5.71)	6.05 (5.66)	−1.45 (0.62); *p* = 0.018 (−2.66 to −0.25)	
12 months	6.40 (6.26)	5.95 (5.51)	−0.24 (0.63); *p* = 0.71 (−1.46 to 0.99)	
PSCS				
Baseline	62.36 (10.92)	63.00 (12.01)	-	
4 months	67.19 (10.77)	69.13 (12.25)	1.76 (1.109); *p* = 0.11 (−0.37 to 3.89)	
12 months	67.43 (12.61)	69.88 (12.32)	3.32 (1.13); *p* = 0.0034 (1.10 to 5.54)	
SFA				
Baseline	12.98 (9.67)	12.91 (9.85)	–	
4 months	8.04 (8.75)	6.62 (7.76)	−1.57 (1.11); *p* = 0.16 (−3.74 to 0.59)	
12 months	6.73 (8.77)	6.05 (7.98)	−0.34 (1.11); *p* = 0.76 (−2.51 to 1.83)	
EQOL5				
Baseline	55.28 (20.44)	55.43 (19.80)	–	
4 months	64.26 (21.55)	66.20 (21.60)	3.303 (1.86); *p* = 0.0077 (−0.35 to 6.95)	
12 months	65.93 (21.71)	68.12 (21.10)	3.48 (1.92); *p* = 0.069 (−0.28 to 7.23)	

a Adjusted for therapist (random effect) and baseline HDRS, parity, education and baseline value of the outcome variable.

TABLE 17 Secondary outcome – treatment response on HRDS (50% or more reduction in baseline score)

Outcome	TAU *n* (%)	PHP *n* (%)	OR (SE); *p*-value (95% CI)
Baseline	–	–	–
4 months	112 (40.1)	158 (56.2)	2.49 (0.76); *p* = 0.003 (1.38 to 4.52)
12 months	151 (58.0)	158 (61.0)	1.07 (0.33); *p* = 0.82 (0.59 to 1.95)

Secondary outcome – improving access to psychological therapies

As of *Table 18*, at 4 months, the treatment (PHP) group were significantly more likely to be satisfied than the TAU group. At 12 months, there was no difference in satisfaction between groups.

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TABLE 18 Secondary outcome – IAPT

	OR (SE); *p*-value (95% CI)
Baseline	–
4 months	2.72 (1.33); *p* = 0.0.40 (1..05 - 7.09)
12 months	2.03 (1.01); *p* = 0.16 (0.77 to 5.40)

Ages and stages questionnaire

The ages and stages questionnaire is a parent completed measure of childhood development in five domains. These data were collected at baseline and 12 months to evaluate the feasibility of using the questionnaire in future studies with British South Asians. However, there are limited data on this variable as it was included later in the study and was lengthy to complete. It was collected only at follow-up for 47 children. *Table 19* shows the average age and score for the children in each domain and in each allocation group. Higher scores indicate better child development; generally scores above 40 suggest that the child's development is on schedule.

TABLE 19 Ages and stages descriptive statistics

	Follow-up – 12 months		
	TAU (*n* = 18) *M* (SD)	PHP (*n* = 19) *M* (SD)	Overall *M* (SD)
Age of child (months)	8.9 (5.74)	8.7 (5.29)	8.8 (5.44)
Communication	45.8 (19.57)	48.2 (11.21)	47.0 (15.66)
Gross motor skills	43.3 (18.15)	50.8 (11.21)	47.2 (15.25)
Fine motor skills	50.0 (14.55)	49.2 (13.77)	49.6 (13.96)
Problem solving	52.2 (10.46)	50.3 (15.14)	51.2 (12.93)
Personal social	49.2 (12.16)	52.9 (10.58)	51.1 (11.37)

TABLE 20 Sensitivity analysis – recovery from depression

	TAU, *n* (%)	PHP, *n* (%)	OR (SE); *p*-value (95% CI)
Baseline	0 (0)	0 (0)	–
4 months	105 (29)	138 (38)	1.63 (0.34); *p* = 0.020 (1.08 to 2.46)
12 months	140 (38)	141 (34)	0.97 (0.20); *p* = 0.87 (0.65 to 1.43)

Compliance analysis

We defined compliance as attending at least one session of therapy. Out of those in the treatment group, three-quarters of the participants were considered compliers (*n* = 246). The group of compliers, on average, attending 8.94 sessions. Due to randomisation, we assumed that the proportion of compliers in the treatment group were identical to the proportion of compliers in the treatment group. Using this assumption, we could find the complier average causal effect (CACE) of the primary outcome. The CACE analysis found that the treatment group were 68% more likely to recover from postnatal depression than Group A at 4 months (95% CI 1.06 to 2.65).

Predictors of missing data in primary outcome

The primary outcome at 4 months, recovery from PND, had 23% missing data (*n* = 170). The missing data were approximately equal between allocation groups, with 83 participants having missing data in the control group (23%) and 87 participants with missing data in the treatment group (24%). A series of logistic regression models were run to find if baseline covariates predicted missingness in the primary outcome. The covariates considered were baseline social functioning (SFA), parental competence (PSCS), health rating (EQoI5), depression (PHQ-9), postnatal depression (HDRS), anxiety (GAD-7), education, parity, mother's age, marital status, generation and whether the patient spoke English. None of these variables significantly predicted missingness in the primary outcome, suggesting these data were not MAR. There was a borderline significant effect of baseline parenting sense of competence in missingness of the primary outcome (OR 1.017, 95% CI 1.000 to 1.00; *p* = 0.050).

Sensitivity analysis

A sensitivity analysis was performed with the missing data in the primary outcome. All participants with a missing primary outcome (recovery from depression) were assumed to have not recovered and were coded as depressed. A partially nested, logistic regression random-effects model was performed to estimate the OR of recovery between treatment groups, when missing outcome data were assumed to be a negative outcome. The sensitivity analysis found that at 4 months, those in the treatment group were 63% more likely to recover from PND than the control group, even when assuming all those with missing outcomes were depressed (OR 1.63, 95% CI 1.08 to 2.46). At 12 months, there was no significant difference in the odds of recovery between groups, under this assumption (*Table 20*).

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Chapter 6 Health economic evaluation

Cost of Positive Health Programme intervention

The costs of PHP intervention are reported in *Table 21* by categories of cost across the four study sites and the number of groups covered in each study site. The major PHP cost component was PHP facilitators' payment. They were paid according to PWP bands 4, 5 and 6 for 2.5 hours per session (preparation and session). The second significant cost of PHP intervention was for creche, costing a total of £41,560 for the study. More than 50% of the sessions were delivered in children's centres which did not charge any cost for their spaces. Since using children's centres has opportunity costs for the health and care system, the economic evaluation analysis costed children's centres at the average (mean) costs charged by community venues in the respective site, with a total venue use costs of £25,000. Supervisors were paid at a fixed rate of £25 per hour for 3.5 hours per group, incurring costs of £3670. Training PHP facilitators costed a total of £6620, which includes refreshment costs, venue costs, and PHP trainers pay (two bands seven trainers with an hourly wage of £20.49 for 6 hours per day) and travel. In terms of sites, the major intervention cost was in the North West (£66,660), covering 21 study groups. Adding all together, the PHP implementation costed £151,020, which becomes £3560 per study group. PHP implementation costed an average of £408 per person. For those who attended at least one session, per session costs were £84. Since the economic evaluation is conducted from the health and social care sector perspectives, the PHP cost does not include the £10 per session paid to each PHP arm participant, nor the participants' travel expenses, as these are generally not covered by health and social care in the UK.

Health and social care resource use

Participants were asked to complete an economic patient questionnaire at the baseline and at each follow-up. In addition to information on primary and community healthcare use, they were asked to provide details of any inpatient admissions, outpatient appointments, type of department/disease and any emergency department attendances. The primary cost-effectiveness analyses included all secondary, primary, and community healthcare use besides the costs of the PHP therapy for the intervention arm.

TABLE 21 Positive Health Programme intervention costs (thousand pounds) by cost categories and study sites

	North West	Yorkshire	London	Midland	Total
Venue	4.63	0.83	13.66	5.84	24.95
Supervision	1.84	0.26	1.31	0.26	3.67
Supervisor travel	0.34	0.14	1.63	0.62	2.72
Printing	1.48	0.25	0.93	0.22	2.87
PHP facilitators	25.88	1.76	15.29	3.27	46.20
PHP facilitators' travel	4.16	0.52	1.29	0.00	5.96
Catering	6.91	1.01	7.08	1.47	16.47
Creche	19.19	6.00	14.62	1.75	41.56
Training	2.24	1.11	2.76	0.51	6.62
Total	66.66	11.86	58.56	13.94	151.02
Number of groups	21	3	15	3	42
Per group cost	3.174	3.953	3.904	4.647	3.596
Per person cost	0.3944	0.3826	0.4039	0.5574	0.4082

Since most of the PHP sessions were covered in 2018 and 2019, unit costs of 2018–9 were used for costing the use of secondary, primary and community healthcare resources (see *Table 22*). Under the 'Other community and social health services' heading in *Table 22*, few participants mentioned an initial psychiatric assessment or psychiatrist. These were costed at the unit cost of 'mental healthcare clusters initial assessments' from National Cost Collection 2018–9. Other resource uses such as visits to religious places and support workers were costed at the hourly rate of 'support and outreach worker' from PSSRU 2019. Elective and non-elective inpatient admissions were costed at the respective average unit cost on a finished consultant episodes basis.

Table 23 reports the headline mean per person secondary, primary and community healthcare resource utilisation costs. Except for the GP surgery attendances, the use of primary and community health care remained very low in both the intervention and control arms. The mean attendance of GP surgery was 1.10 per person at the baseline in the intervention arm versus 1.07 in the control arm. In the post-intervention period, GP surgery attendances fell by 0.03 points in each arm. The mean number of counsellor visits was 1 per 100 persons in the intervention arm versus 2 per 100 persons in the control arm at the baseline. In the post-intervention period, it became zero for the intervention arm versus 1 per 100 persons in the control arm. There was no change in the use of other community mental health services in the intervention arm over the study period, whereas the use increased from zero to 1 per 100 persons in the control

TABLE 22 Unit costs of secondary, primary and community healthcare resource (2018–9)[a]

Service type	Unit costs (£)	Source
GP surgery	39.1	PSSRU[111] 2019 (GP cost per surgery consultation lasting 9.22 minutes, including direct care staff costs, including training)
GP home	78.92	PSSRU 2014 and PSSRU 2019 [£156 per hour of GMS activity, 11.4 minutes visit, 1:0.61 direct-to-indirect time ratio (7.0 minutes indirect), 12 minutes travel]
Practice nurse surgery	12.43	PSSRU 2014 and PSSRU 2019 (£37 per hour, 15.5 minutes per contact, 1:0.30 direct-to-indirect time ratio)
Practice nurse home	39.68	National Cost Collection 2018–9 (N02AF – district nurse, face to face)
Walk-in centre	21.00	PSSRU 2019 (assume 15 minutes of band 6 nurse time)
Counsellor	45.00	PSSRU 2019 (agenda for change band 6 for 1 hour)
Other community mental health services	44.00	PSSRU 2019 (community occupational therapist 1 hour)
Other community and social health services	62.90	If physiotherapy: National Cost Collection 2018–9 (A08A1 – physiotherapist, adult, one to one)
	304.00	If psychiatric assessment: National Cost Collection 2018–9 (mental healthcare clusters initial assessments)
	24.00	Others: PSSRU 2019 (support and outreach worker for 1 hour)
Inpatient admissions	4077.93	National Cost Collection 2018–9 [national average unit cost of elective inpatients (FCEs)]
Outpatient visits	126.85	National Cost Collection 2018–9 (national average unit cost of outpatient attendances)
Day cases	751.90	National Cost Collection 2018–9 (national average unit cost of day cases)
A&E attendances	166.05	National Cost Collection 2018–9 (national average unit cost of A&E attendances not leading to admission)
Emergency admissions	3292.75	National Cost Collection 2018–9 [national average unit cost of non-elective inpatients (FCEs)]

PSSRU, Personal Social Services Research Unit
a Primary and community care unit costs and length of visits are taken from different PSSRU issues and converted to the year 2018–9 prices.

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TABLE 23 Mean secondary, primary and community healthcare costs by trial arms and time points (2018–9£)

	PHP arm			Control arm		
	Mean	SD	Participants	Mean	SD	Participants
Baseline						
Elective and A&E admissions	507	1466	338/338	485	1347	333/334
Outpatient/day case/A&E attendances	47	238	338/338	61	299	333/334
Secondary care total cost	554	1515	338/338	546	1452	333/334
Primary care	49	70	336/338	45	65	333/334
Community care	3	16	338/338	2	17	333/334
Total healthcare cost	606	1531	338/338	593	1462	333/334
4-month follow-up						
Elective and A&E admissions	288	1654	276/338	201	928	276/334
Outpatient/day case/A&E attendances	111	421	277/338	81	420	278/334
Secondary care total cost	398	1892	277/338	280	1024	278/334
Primary care	47	72	279/338	51	84	276/334
Community care	3	21	278/338	3	13	277/334
Total healthcare cost	445	1918	279/338	334	1048	278/334
12-month follow-up						
Elective and A&E admissions	151	806	255/338	154	836	260/334
Outpatient/day case/A&E attendances	98	432	256/338	46	247	261/334
Secondary care total cost	248	976	256/338	199	922	262/334
Primary care	32	57	254/338	27	45	260/334
Community care	4	21	256/338	4	17	262/334
Total healthcare cost	284	996	256/338	229	930	262/334

arm. The use of secondary care was higher in the intervention arm compared with the control arm both at the baseline and at each follow-up.

Health outcomes

Health benefits were quantified by QALYs estimated from responses to the EQ-5D-3L questionnaire. QALYs were calculated from time-weighted linear interpolation of the baseline, 4- and 12-month follow-ups utility indices. *Table 24* gives a summary of the resultant utility index and QALYs by trial arm and time points of the study. The mean baseline utility of the intervention arm is 2 points lower than the mean utility of the control arm. The difference increased to 3 points in favour of the PHP group at the 4-month follow-up but decreased at the 12-month follow-up. *Figure 4* plots the mean utilities for each point in time. This figure contains data for complete cases at each time point, so the difference in utilities in *Figure 4* is partly due to differences in the number of participants at the 3 points of time caused by missing data.

TABLE 24 Utility scores and QALYs by trial arm and time point (complete cases across time)

	Mean	SD	Median	Minimum	Maximum	Participants	Missing data (%)
Intervention arm							
12 months	0.78	0.26	0.85	−0.18	1.00	214	42
4 months	0.75	0.30	0.81	−0.59	1.00	214	42
Baseline	0.58	0.30	0.69	−0.35	1.00	214	42
QALY	0.73	0.21	0.77	0.03	1.00	214	42
Control arm							
12 months	0.78	0.30	0.85	−0.22	1.00	214	41
4 months	0.72	0.29	0.80	−0.18	1.00	214	41
Baseline	0.60	0.32	0.69	−0.48	1.00	214	41
QALY	0.72	0.23	0.78	−0.04	1.00	214	41

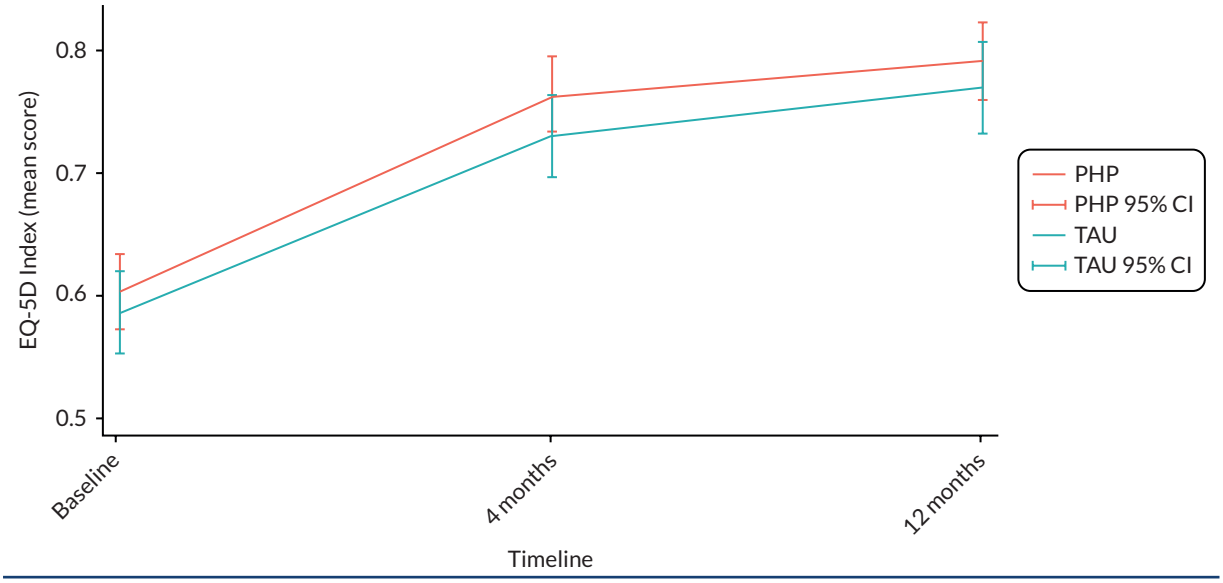

FIGURE 4 Trends in utility scores by trial arms (complete cases at each time point).

Missing data

Logistic regressions showed that missingness indicators of the cost components and utility at the 4- and 12-month follow-ups were not associated with baseline demographics like employment, qualification, and marital status. Some of the missing cost components and utilities at the 4- and 12-month follow-ups were associated with the baseline inpatient admission costs and baseline costs of GP surgery. Nevertheless, the association was statistically significant only at a 10% significance level. In some regressions, missingness was significantly different across study sites, with proportionally more missing data in two study sites. This suggests that the data were not missing completely at random (MCAR).[110] Covariates-dependent missingness or MAR seemed to be a more plausible assumption.[112] The sensitivity analysis then introduced two deviations from the MAR assumption to see how the results of the multiply imputed data are affected.

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Given the amount of missing data, 50 imputed data sets were created. For comparison, *Table 25* reproduces the utility and QALYs statistics on the imputed data. Comparing *Tables 24* and *25*, the mean of the imputed data is greater than the respective mean in the unimputed data only for the intervention arm. This seems to suggest that at the 12-month follow-up, the missing data in the intervention group were mostly for those with higher utility values at the baseline. The difference in *Tables 24* and *25* remained irrespective of whether the imputations were carried on the utility index or the responses to EQ-5D-3L five dimensions.

Incremental cost and effects (QALYs)

Table 26 reports incremental costs, incremental QALYs, incremental cost-effectiveness ratio (ICER) and incremental net monetary benefits of PHP intervention. The PHP resulted in a 0.02 increase in QALYs per person over the 12 months. The associated incremental cost of the PHP group was £549.68 per person. This means that the average person in the PHP group cost £549 more than the average person in the TAU group. Most of this cost was due the cost of PHP implementation (£408 per person). Based on the QALY health gains, the mean incremental cost per incremental QALY was £22,198. This indicates that gaining one additional QALY with PHP versus TAU is associated with a mean total cost of £22,198. The uncertainty analysis indicates that the probability that PHP would be cost-effective is 44% (56%) if decision-makers are prepared to pay £20,000 (£25,000) to gain one QALY. At £25,000 willingness to pay, the mean net monetary benefits from PHP were £69 (*Table 26*).

Uncertainty

To assess uncertainty of estimates, incremental costs and QALYs were non-parametrically bootstrapped with 5000 replications. *Figure 5* presents the cost-effectiveness plane to depict the uncertainty around the mean incremental costs and QALYs. The bootstrapped results suggest that 96% of the replications lie within the northeast quadrant. This suggests that PHP intervention for PND increased both costs and QALYs in most of the replications. In 4% replications, PHP intervention increased cost but had no or negative effects on QALYs. *Figure 6* presents the likelihood that PHP was cost-effective at different willingness-to-pay values. With reference to NICE range, the probability that PHP would be cost-effective is 44% at £20,000 and 65% at £30,000.

Incremental cost and effects (remission)

Cost-effectiveness analyses were run with the primary clinical outcome measure (HDRS score of ≤ 7 vs. HDRS score of > 7) at the 4- and 12-month follow-ups to explore the cost per remission from PND. The cost and effects regressions were jointly estimated, but now the effects regression was estimated with logistic regression as the outcome measure is a binary indicator. The results are reported in *Table 27*. The PHP intervention was found to have significant effects on remission from PND after 4 months of PHP intervention. The odds of remission from depression in the PHP intervention group were higher by a factor of 1.71 compared with the TAU group at the 4-month follow-up. This suggested an incremental cost of £4550 per remission from PND among South Asian women at the 4-month follow-up.

TABLE 25 Utility scores and QALYs by trial arm and time point (imputed data)

	Mean	SE	90% lower CI	90% upper CI	Participants
Intervention arm					
12 months	0.8011	0.0017	0.7982	0.8039	368
4 months	0.7659	0.0020	0.7626	0.7693	368
Baseline	0.6039	0.0022	0.6002	0.6075	368
QALY	0.7506	0.0014	0.7483	0.7529	368
Control arm					
12 months	0.7665	0.0022	0.7629	0.7702	364
4 months	0.7341	0.0020	0.7307	0.7374	364
Baseline	0.5870	0.0023	0.5832	0.5909	364
QALY	0.7204	0.0016	0.7178	0.7230	364

TABLE 26 Regression results of incremental costs and QALYs

	Costs estimate		QALYs estimates	
	Coefficients	95% CI	Coefficients	95% CI
PHP	549.68	231.18 to 868.19	0.02	−0.01 to 0.06
Baseline costs	0.11	−0.01 to 0.24	−0.00	−0.00 to 0.00
Baseline utility	−444.80	−899.09 to 9.48	0.31	0.26 to 0.35
Age	3.73	−16.90 to 24.36	−0.00	−0.00 to −0.00
Primary/GCSE/A level	−184.96	−607.31 to 237.40	0.04	−0.00 to 0.09
First/higher degree	−381.95	−802.57 to 38.66	0.06	0.02 to 0.11
Site 2	235.96	−190.49 to 662.40	−0.09	−0.15 to −0.04
Site 3	−47.92	−370.60 to 274.76	−0.07	−0.12 to −0.01
Site 4	−150.21	−547.25 to 246.83	−0.07	−0.13 to −0.00
Incremental cost/QALY gained		£22,198		
Net benefit (95% CI) WTP = £20,000		£−54 (£−776 to £667)		
Probability PHP cost effective at WTP = £20,000		0.4411		
Net benefit (95% CI) WTP = £25,000		£69 (£−791 to £930)		
Probability PHP cost effective at WTP = £25,000		0.5630		
Net benefit (95% CI) WTP = £30,000		£193 (£−809 to £1195)		
Probability PHP cost effective at WTP = £30,000		0.6476		

WTP, willingness to pay.

Note
Standard errors are partially clustered (at PHP group level) to account for within PHP group correlation. Both equations are simultaneously estimated using Seemingly Unrelated Regression.

However, the PHP incremental effects on HDRS scores remained lower and statistically insignificant at the 12- month follow-up, with an ICER of £60,221.98. The higher ICER at the 12-month follow-up is not surprising, as the difference in remission does not persist at this point.

Sensitivity analysis

Table 28 contains different sensitivity analyses. The loss to follow-up or missing observations might not be random. Among other reasons, the participants might not participate at the follow-ups due to either remission from PND or deterioration in their health. Columns 1 and 2 of *Table 28* introduce two deviations from the MAR assumption that was used to impute the missing data. Column 1 (best-case scenario) assumes that the missing utility values are 10% higher than the ones imputed through multiple imputations, and the missing costs are 10% lower than the imputed costs. Column 2 (worst-case scenario) deviation from MAR is the opposite of column 1. The PHP under the best-case scenario resulted in a 0.03 increase in QALYs per person over the 12 months. Compared to *Table 26*, ICER now dropped to £20,733, and the probability that PHP is cost-effective is 48% (60%) if decision-makers are prepared to pay £20,000 (£25,000) to gain one QALY. Under the worst-case scenario in column 2, ICER jumped up to £23,879, and the probability PHP is cost-effective dropped to 40% (52%) at the willingness to pay of £20,000 (£25,000) to gain one QALY.

Incremental costs, effects and ICER for the complete cases are reported in column 3 and incremental costs, effects and ICER estimates after excluding secondary care use are reported in column 4 of *Table 28*. In complete case analysis, the PHP intervention resulted in a positive incremental cost and incremental QALYs gains. The resultant ICER is £29,459. Nevertheless, as discussed earlier, the missing data were not likely to be MCAR. Thus, we would not recommend relying

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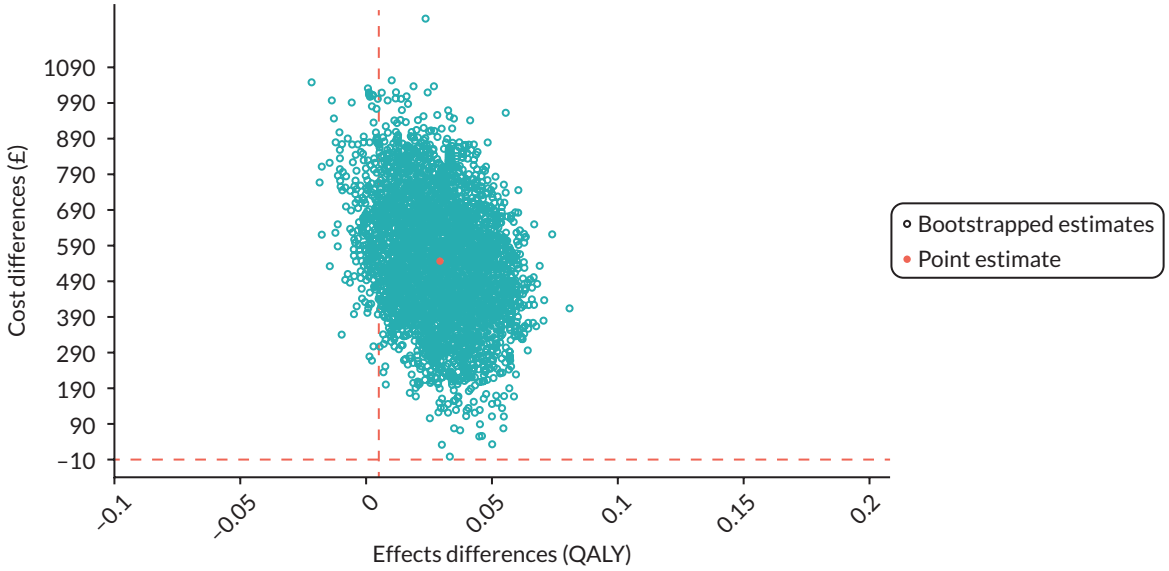

FIGURE 5 Cost-effectiveness plane (bootstrapped with 5000 replications).

on the results of the complete cases. After excluding secondary care use costs, the ICER dropped to £16,961. This is because of the relatively higher secondary care use among the PHP arm participants.

Additional analysis

The PHP intervention comprised 12 sessions and was delivered in a group format. In such programmes, the group size and the optimal number of sessions are important factors in cost-effectiveness. One key question, therefore, is whether there is any minimum threshold of sessions that must be met for the PHP intervention to be effective. Similarly, what might be the maximum number of sessions beyond which the incremental health effects of additional sessions become insignificant, or the costs become increasingly high. The latter question is fundamental in any group learning environment. As the programme progresses, the number of participants will likely fall either because they will recover or the intervention might not fit their purpose. But the costs would not fall by the

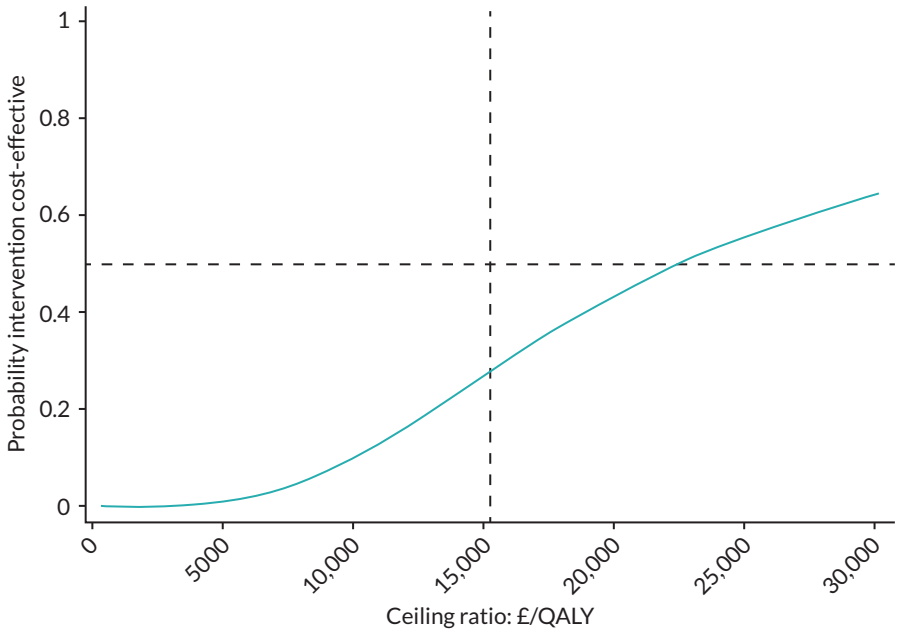

FIGURE 6 Cost-effectiveness acceptability curve for the cost per QALY gain.

TABLE 27 Regression results of incremental costs and HDRS

	Costs effects estimate		HDRS effects estimates	
	Coefficients	95% CI	Odds ratios	95% CI
Effects at the 4-month follow-up				
PHP	569.08	255.74 to 882.43	1.71	1.17 to 2.50
Incremental cost/remission		£4550.73		
Effects at the 12-month follow-up				
PHP	551.55	232.68 to 870.41	1.04	0.72 to 1.51
Incremental cost/remission		£60,221.98		

Note
Standard errors are partially clustered (at PHP group level) to account for within PHP group correlation. The estimations adjust for baseline HDRS, costs, age, qualification and study sites (to save space all covariates are not reported).

same ratio or might not change at all. This will mean increasing per-person costs if the group continues to shrink. Similarly, existing literature suggests that postpartum patients must attend 5–8 sessions to realise the positive effects of such therapies.[113] Depression and QALYs being strongly linked imply that the healthcare use and quality of life effects of PHP might be different for those attending varying numbers of sessions.

TABLE 28 Deviations from missing at random assumption and complete case analysis

	1[a]	2[b]	3[c]	4[d]
Incremental QALY effects	0.03	0.02	0.02	0.02
95% CI	−0.01 to 0.06	−0.01 to 0.05	−0.02 to 0.06	−0.01 to 0.05
Incremental cost effects	548.66	550.71	652.49	405.00
95% CI	242.11 to 855.20	219.44 to 881.98	262.11 to 1042.87	364.23 to 446.00
ICER	£20,733	£23,879	£29,459	£16,961
NMB at WTP = £20,000	£−19	£−89	£−209	£73
95% CI	£−758 to £720	£−801 to £622	£−1199 to £780	£−525 to £670
Probability PHP cost-effective	0.48	0.40	0.34	0.59
NMB at WTP = £25,000	£112	£25	£−98	£192
95% CI	£−771 to £997	£−821 to £873	£−1281 to £1083	£−552 to £936
Probability PHP cost-effective	0.60	0.52	0.43	0.69
NMB at WTP = £30,000	£245	£141	£12	£311
95% CI	£−786 to £1277	£−844 to £1126	£−1366 to £1390	£−580 to £1203
Probability PHP cost-effective	0.68	0.61	0.51	0.75

NMB, net monetary benefits.
a Best-case scenario: missing costs = 0.9 × model predicted cost, missing utility = 1.1 × model predicted utility.
b Worst-case scenario: missing costs = 1.1 × model predicted cost, missing utility = 0.9 × model predicted utility.
c Estimations based on complete cases only.
d Estimations excluding secondary care use.

Note
Standard errors are partially clustered (at PHP group level) to account for within PHP group correlation. The estimations adjust for baseline utility, costs, age, qualification and study sites. Both equations are simultaneously estimated using Seemingly Unrelated Regression.

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Following the findings in Forde *et al.*,[113] we have divided the PHP participants into three groups based on the number of attended PHP sessions. *Figure 7* presents mean utility scores for three different bands of completed sessions. Those who completed up to four sessions had a better mean utility score at baseline compared with the baseline mean scores of the other two bands. Nevertheless, the one with more than four completed sessions had better outcomes in the post-intervention period. This implies that participants with greater need (with poorer health at the baseline) had taken more sessions than those with relatively better health, and seemed to benefit more from the PHP intervention.

To formally check the dose–response relation and the associated costs, the incremental cost and effects regressions were rerun with the intervention indicator now replaced by a categorical variable on the completed sessions. From *Table 29*, four or fewer completed sessions have no incremental effects on QALY. Thus, this group is strictly dominated by the control arm. For the group who participated in 5–8 sessions, the PHP resulted in a 0.04 increase in QALYs per person. The associated incremental cost of PHP was £387 per person. Based on the QALYs health gains, the ICER was £9,040. At £15,000 WTP to pay, the mean net monetary benefits from PHP were £255 for this group (*Table 29*). For uncertainty check, *Figure 8* plots cost-effectiveness acceptability curves for each of these groups of participants. From the figure, one can see that the probability of PHP is cost-effective for the group with 5–8 sessions is 73% (81%) if decision-makers are prepared to pay £15,000 (£20,000) to gain one QALY. This analysis indicates that QALYs continue to increase with the number of attended PHP sessions. Nevertheless, the incremental positive effects get smaller with additional sessions. Resultantly, 5–8 therapy sessions are more cost-effective than 9–12 sessions.

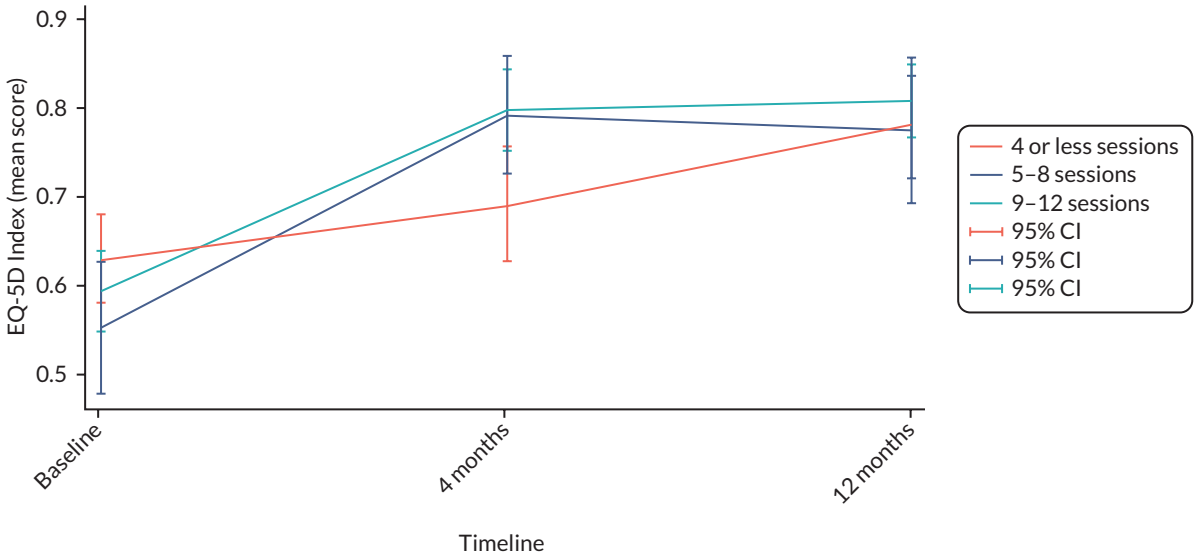

FIGURE 7 Utility scores by completed sessions and time.

TABLE 29 Regression results of incremental costs and QALYs with completed sessions

	Costs effects	QALYS effects	ICER	NMB (WTP = £15,000)
4 or fewer sessions	528.94	−0.00	–	–
95% CI	175.20 to 882.68	−0.05 to 0.04		
5–8 sessions	387.26	0.04	£9040	£255
95% CI	−30.83 to 805.36	−0.00 to 0.09		£−584 to £1095
9–12 sessions	667.54	0.05	£13,127	£95
95% CI	162.78 to 1171.27	0.02 to 0.08		£−658 to £848

Note
The standard errors are clustered at group level to account for within group correlation. The estimations adjust for baseline utility, costs, age, marital status and employment status of the study participants. It includes group-level random intercepts to correct for any within group nesting.

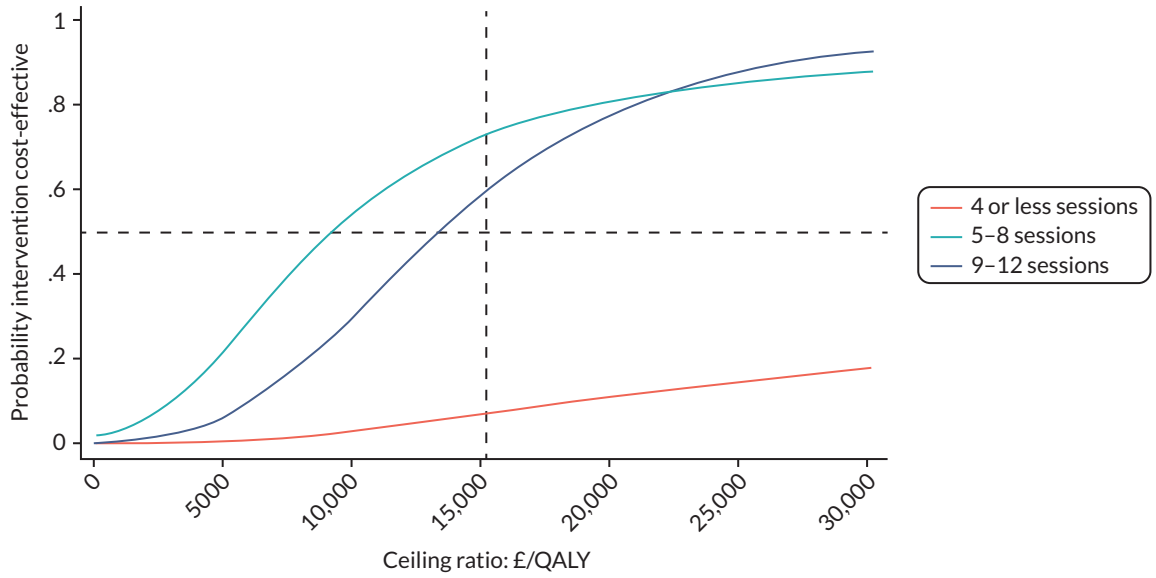

FIGURE 8 Cost-effectiveness acceptability curves by number of sessions.

Since PHP intervention costs were incurred at the group level and were equally divided among the group members, the low cost for 5–8 sessions means that they have either low healthcare use or belongs to groups of low PHP costs. Looking at the data indicated that the per person PHP costs for those with 9–12 sessions were £433 compared to PHP costs of £407 for those with 5–8 sessions. The healthcare uses costs were also higher for those with 9–12 sessions compared with participants who attended 5–8 sessions.

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Chapter 7 Qualitative study – (main trial) findings

Introduction

The aim of this qualitative study was to explore the views and perspectives of BSA women, PHP facilitators and GPs on the usefulness of the PHP intervention and how participants experienced it. The study examined the PHP's perceived feasibility, acceptability, and sustainability for managing PND in BSA women in primary care settings. The findings from the PHP RCT (see *Chapter 5*) revealed a statistically significant difference in the primary outcome of depression severity (PHQ-9) between trial arms at 4-month follow-up in support of PHP intervention but not at 12-month follow-up. The qualitative data reported here provides an understanding of acceptability of the intervention components using TFA:[105] affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

Objectives

1. To examine the acceptability of the group intervention from the perspective of BSA women and their families.
2. To explore views of the GPs on the group psychological intervention and its impact on practice.
3. To explore perspectives of PHP group facilitators about training and delivery of the intervention.

Methods

Design

Semistructured interviews were conducted with trial participants, withdrawn participants, PHP facilitators and GPs to gather in-depth information on how they perceived the acceptability, engagement, and implementation of PHP intervention. The participants shared their views and experiences of receiving PHP, while PHP facilitators shared their experiences and opinions on delivering the PHP intervention. Interviews with GPs explored their experiences of working with BSA women with PND. Interviews were conducted with trial participants, PHP facilitators and GPs at the end of the intervention period.

Inclusion criteria

Withdrawn trial participants

- Participants who were randomised to the intervention arm and withdrew before completing four sessions of the intervention.

Trial participants

- Participants who were randomised to the intervention arm.
- Participants who attended at least one or more sessions of the PHP.

Positive Health Programme facilitators

- Positive Health Programme facilitator who delivered at least one course of the PHP.

General practitioners

- General practitioners whose practices participated in ROSHNI-2 study.

Trial participants

For the interviews, trial participants were purposively sampled from the PHP intervention trial database, aiming for variation in terms of geographic location, age, socioeconomic status, and ethnicity to enable an in-depth exploration of the perceived impact of the PHP intervention.

Withdrawn trial participants

Trial participants who withdrew were purposively sampled from the trial database to further explore the reasons for discontinuing the PHP trial. Qualitative researchers re-engaged with withdrawn participants by telephone or letter (adhering to their stated contact preferences) to ask if they would consider participating in an interview. Those participants who agreed were sent an information pack, which included a PIS. Potential participants were contacted again after approximately 1 week to confirm whether they would be willing to participate.

Positive Health Programme facilitator participants

Qualitative researchers phoned or e-mailed all GPs and PHP facilitators to ask if they would be willing to participate in an interview. Interested individuals were e-mailed a PIS with information about the qualitative study.

General practitioner participants

General practitioners involved in the trial were e-mailed to participate in an interview. Interested individuals were e-mailed a PIS with information about the interview study.

Study materials

With input from patient and public involvement, the research team developed separate sets of topic guides for trial participants, PHP facilitators and GPs during the internal pilot period. These topic guides were further refined after the completion of interviews in the internal pilot to inform the interview topic guides in the main trial.

Data collection

Qualitative researchers conducted interviews at a convenient place and time according to participant preferences, either face-to-face interviews at the participant's home, in neutral settings, such as a children's centres or community centres, or over the telephone. With the consent of participants, all interviews were audio-recorded, transcribed verbatim, and anonymised before data analysis. The recruitment period for the qualitative study was from February 2017 to March 2020.

Qualitative data analysis

Initially, the data analysis plan was to utilise a framework analysis, however, the research team employed thematic analysis to discern and highlight significant themes. The themes were subsequently applied to the TFA, specifically focusing on assessing the intervention's acceptability across the seven domains outlined within the framework. This dual methodology facilitated a comprehensive exploration and evaluation of the intervention's acceptability within the study's specific context.

Interviews conducted in English were transcribed verbatim. However, interviews conducted in languages other than English were translated into English and then transcribed verbatim by the qualitative researchers; and analysed by two qualitative researchers. The transcripts were read to identify key themes linked with the qualitative study's aims. An iterative procedure was used to generate new codes, and specified codes were developed as the analysis progressed. After completing the initial coding, the codes were reduced into various themes. The specified key themes focussed on both parts of the study: the support experiences of trial participants and the perceived effectiveness of PHP (trial participants, PHP facilitators and GPs in the intervention arm). After that, transcripts were revisited, and the first qualitative researcher identified developing subthemes within each central theme with the second researcher and through ongoing discussions to agree on, and finalise, themes.

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The GP interviews were analysed using only thematic analysis to identify key themes. For the trial participants and the PHP facilitators' interviews, the researchers deductively charted the themes into the seven acceptability domains in the TFA.[107] The TFA was used to analyse the trial participant's and PHP facilitators' data. The TFA is a multiconstruct theoretical framework that can be applied to assess the retrospective acceptability of healthcare interventions from the perspective of intervention recipients. The TFA consists of seven component constructs. These seven components were used as a framework for analysis: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

To enhance reliability, all interview transcripts were coded in NVivo by the first qualitative researcher; then, transcripts were coded by the second qualitative researcher. The experiences of participants were charted to summarise and link to the matching themes and subthemes. Both qualitative researchers met to discuss the identified themes, and the discussion continued until a consensus was reached. Descriptive quotes were included to support the validity of the findings.

Results findings

A total of 61 participants were purposively sampled for interview purposes (32 trial participants, 13 withdrawn participants, 11 PHP facilitators and 5 GPs). These participants were chosen based on their relevance and significance to the research objectives.

Interviews with participants lasted between 30 and 60 minutes. Interviews with PHP facilitators and GPs took place over the phone and face to face. PHP facilitators and GPs' interviews lasted between 30 and 60 minutes. Where appropriate, women who did not speak English were interviewed in their preferred language with either an interpreter or a bilingual interviewer. Following the interview, trial participants were offered a £20 shopping voucher to thank them for participating.

In total, 35 interviews were conducted as part of the study. These interviews encompassed a diverse range of participants, including 17 trial participants and 2 withdrawn participants, 11 PHP facilitators and 5 GPs. The trial participants demographics is detailed in *Table 30* and details of the PHP facilitators in *Table 31* and GPs across the different regions in *Table 32*.

The findings are reported under the seven domains of the TFA:[105] affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy. These are explored in detail below, and descriptive quotations illustrate the interview data findings.

Affective attitude – how an individual feels about taking part in the intervention

Trial participants reflected on how they initially felt about being invited to participate in the PHP. They discussed initial concerns about confidentiality and, how the members of their community and family network would perceive them, and developing self-confidence to talk about themselves with others in a group setting:

> *I thought people would judge me … I never attended group counselling … everyone else will know your problems and I know they are not supposed to share it, but they might share it.*
>
> *Trial participant MD-003*

Most of the trial participants we interviewed expressed positive attitudes about the intervention. Participants highlighted the specific positive therapeutic content of the intervention. Also, they voiced a general appreciation of the non-therapeutic specific elements such as child-care facilities, refreshments, time away from their daily routine and the opportunity to meet with other women:

> *It was a treat honestly … good food, childcare I made friends learnt some very good things which help me in my daily life … Truly it was time for me, I will always remember it. Everything was really good. Can't be thankful enough, these sessions have really changed my life.*
>
> *Trial participant LO-003*

TABLE 30 Qualitative study – trial participants' characteristics (including withdrawn participants)

Characteristics	*N* = 19
Age	
18–25	1
26–35	14
36–45	4
46 +	0
Ethnicity	
Bangladeshi	2
Pakistani	11
Indian	5
Sri Lankan	1
Trial region	
North West	4
East Midlands	5
London	6
Yorkshire	4

TABLE 31 Qualitative study – PHP facilitators' characteristics

Characteristics	*N* = 11
Ethnicity	
Bangladeshi	3
Pakistani	6
Indian	2
Sri Lankan	0
Trial region	
North West	1
East Midlands	4
London	5
Yorkshire	1
Educational attainment	
Postgraduate	4
Master's and postgraduate certificate	3
Competence-based qualification	3
Information missing	1

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TABLE 32 Qualitative study – GPs' characteristics

Characteristics	*N* = 5
Ethnicity	
Bangladeshi	0
Pakistani	4
Indian	0
Sri Lankan	1
Trial region	
North West	3
East Midlands	0
London	2
Yorkshire	0

PHP facilitators with South Asian heritage discussed how they were inclined to apply for the advertised PHP facilitator's role to work specifically with BSA women. They highlighted their interest in the project due to its explicit nature in targeting BSA women and maternal mental health, highlighting this as an area requiring greater attention and health support from health professionals:

> *When I applied for the job, it sorts of appealed to me because it was working with the ethnic minority community. I think that's an area that we do need to sort of tackle and raise awareness of the stigma that is associated with mental health and especially maternal mental health. So that's sort of like why I wanted to sort of go forward for the role.*
>
> *PHP facilitator WY-008*

Similarly, another PHP facilitator reported:

> *I just generally think it's a good piece of intervention especially in terms of developing and helping the South Asian community and whenever I've gone out and have talked to people about it to some participants or even if it's a professionals or community they always kind of seen it as a really a good therapy which is something needed out there. So, I just think it's a really good initiative.*
>
> *PHP facilitator LO-009*

Participants perceived the intervention as providing a better understanding and resonating with their value systems, whether from the PHP facilitator's or trial participants perspective. Most participants agreed with the idea of the design and strategies used for delivering the intervention:

> *It's just very good, obviously, to have that manual with us because the manual has everything in it. Every part, every exercise, everything even after this is my fifth group as still; I am referring to the manual sometimes. The manual obviously gives us you know readymade guide to deliver the sessions. Quite good obviously the manual is arranged in a way that all of the women can be part of the session.*
>
> *PHP facilitator LO-001*

The data extracts used to illustrate the affective attitude from the PHP facilitator's interviews reflect that PHP facilitators generally felt confident and well equipped to deliver the intervention effectively to ensure that knowledge and understanding are transferred to the women. Their satisfaction with the intervention and connectivity to the individuals' value system shows that such a programme requires invested time and engagement. The intervention was perceived by most participants as acceptable and could produce impactful results for BSA women with PND in the context of inclusivity and raising awareness.

Ethicality – the extent to which the intervention has a good fit with an individual's value system

Many participants discussed the perceived stigma associated with mental ill-health and postnatal depression in the BSA community. A trial participant used the term 'narrow-minded' to describe the BSA community. However, in this context, PHP was primarily seen as a culturally sensitive intervention addressing their value systems and viewed as beneficial:

> *In the Asian community it's a stigma definitely and even people don't understand mental health and they don't look after it as they do about their physical health ... yes, I think they should open up and should tell their family to engage and especially husband and wife can both work together and should support each other.*
>
> *Trial participant WY-003*

> *These sessions were beneficial for me that they kept my confidentiality but also provided me with right support that I was looking at that time. I had family support, but I am talking about professional support as I also work in health care, and I know the importance of professional support, so these sessions benefited me a lot.*
>
> *Trial participant WY-004*

Intervention coherence – the extent to which the participant understands the intervention, and how the intervention works

Prior to starting the intervention, most participants' viewed PHP as a support tool that would enable them to address their condition and/or facilitate problem-solving and understood its intended purpose:

> *I thought then that I am depressed, and it might help me as I was looking for some support to get me out of my poor situation.*
>
> *Trial participant LO-003*

Participants reflected on what they had understood about PHP through the sessions they had attended:

> *Each session was about a different topic … so it explored different things, one I think was assertiveness, saying no to certain things I think that helped me a lot … it was basically working on yourself, and trying to identify the problems you have to build your self-esteem back up, so that helped yeah. I did work on my self-esteem and also started saying 'No' when I wanted to.*
>
> *Trial participant MD-003*

In addition, most PHP facilitators reiterated the importance of the intervention for BSA women. One PHP facilitator shared her thoughts on how her own life experiences resonated with trial participants' circumstances:

> *When I heard about this study, I said this is something very close to my heart and I want to work with at that, and being a mum, being a British Asian woman I can understand what it feels like, don't have your family here and the challenges and the problems one faces when we have a baby without any support and sometimes we have support but it's what we go through so it's quite close to me as well.*
>
> *PHP facilitator MD-013*

Most of the PHP facilitators stated the importance of improving the mental health of the BSA community, especially the needs of participants who recently immigrated and were tasked with the families' household chores and responsibilities:

> *The South Asian British women, who are coming, I mean, from the group we had, I realised that, when mums, mostly mums have come from Bangladesh or India or Pakistan. And then they come here, they don't have a family support over here, so that they have to do everything on their own and there's already too much on their plate that they have to look after the family they have to do household chores and then the baby. The mother is already so tired and there is so much psychological adjustment to motherhood, that no one, no one else is able to understand that.*
>
> *PHP facilitator LO-009*

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Positive Health Programme facilitators talked about their satisfaction with the training, which added value to their understanding of the intervention. Subsequently, many seemed to understand the aim of the intervention clearly and felt confident in delivering the intervention. PHP facilitators viewed the objective of the PHP to help BSA women to be active, and a few PHP facilitators highlighted that particular session on confidence building, assertiveness and self-esteem were favoured highly by many of the trial participants:

> *I think most of the women at the end of our sessions in the last two sessions we ask if they want to repeat any sessions? That they really enjoyed and want to go back to and for me I think it has been the confidence and assertiveness and the self-esteem one, these are the two areas that mums really like to focus on.*
>
> *PHP facilitator NW-001*

Burden – the perceived amount of effort that is required to participate in the intervention

Managing attendance at the sessions and balancing child-care needs was perceived as challenging by a number of trial participants; which was reflected in their limited availability to attend all sessions:

> *I have other kids, and I was concerned about them although they provided the taxi and as well as crèche which was really very good. It was just that I was concerned about my kids, so I became less interested, and this made me skip the sessions.*
>
> *Trial participant WY-001*

In contrast, PHP facilitators perceived their attendance as requiring little effort and not very difficult overall to attend and deliver PHP sessions, mainly due to the group delivery approach used:

> *It was not that difficult for facilitating because most of the women who were part of the group where you know recruited by myself, sometimes by myself and sometimes by others and we went to zero visits. For zero visits where you go and invite them, and that part made me familiar with these women and obviously made me confident to go in front of them and obviously facilitate the training.*
>
> *PHP facilitator LO-001*

Opportunity costs – the extent to which benefits, profits, or values must be given up engaging in an intervention

Although child-care and benefits such as taxi fares for transportation and refreshments were provided to trial participants, PHP facilitators indicated that a few women could not attend some sessions for various other reasons:

> *And that's just down to individual circumstances, you know the babies falling ill or the mums are or falling ill but there were a few mums who didn't attend all the session you know when you just can't be bothered.*
>
> *PHP facilitator NW-002*

Some PHP facilitators highlighted how it was easier to engage the women and retain them during the intervention; however, they struggled with a lack of co-operation from the trial participant's family members, head of household, especially spouses of women.

Perceived effectiveness – the extent to which the intervention is perceived as likely to achieve (or have achieved) its purpose

Most trial participants perceived the PHP intervention as likely to achieve its purpose:

> *I am feeling so much better … I got a lot of confidence, and I was a bit hesitant to communicate with other people in public, but I don't hesitate now … I don't even fight with my husband anymore, only thing to complain about was I wake early and sleep late.*
>
> *Trial participant LO-005*

However, other trial participants reflected that although PHP was perceived as effective, their low mood still persisted:

> *I feel good but sometimes you just feel like … you don't have the support there when sometimes you feel low … it's made me think how to improve myself, help myself so I think that same time it helped me with my depression so it's made me do more things … it will take some time obviously to deal with everything but it's getting better.*
>
> *Trial participant MD-003*

Closely linked to trial participants' views on intervention coherence, PHP facilitators also observed that group intervention helped trial participants. The group interaction with other BSA women with similar experiences, motivated each other to increase their physical activity and boost their self-esteem, and establish trusting relationships:

> *The research study and the results prove from the feedback of women and the way we noticed changes in them when we see them on the screening and during SCID assessment and on celebrations day, session eleven and celebration day we could tell the difference from majority of moms.*
>
> *PHP facilitator NW-002*

Self-efficacy – that participant's confidence in change of behaviours using Positive Health Programme

Participants talked about their learning from PHP, for example, using time more effectively, being assertive, and planning self-care. Self-efficacy findings defined the PHP facilitator's confidence in delivering the intervention sessions. Most PHP facilitators reported feeling confident about providing and completing the sessions effectively. PHP facilitators' views were consistent in delivering the sessions confidently and taking control of the sessions that brought an unprecedented change in the participants and improved their self-esteem.

Positive Health Programme facilitators reported satisfaction in terms of training that prepared them effectively in delivering the sessions and appreciated the opportunity to be trained before delivering the sessions:

> *At the beginning I was a bit apprehensive like to run a group because I hadn't really done that before so I was wondering like would I be able to do it. Like we had the manual as well so we just worked through that and most of the time I was co-facilitator but there were parts when the lead facilitator was off sick and stuff, so I had to do the group on my own. So, I think that really developed my confidence and I was able to run the programme.*
>
> *PHP facilitator NW-001*

The PHP facilitators noted that most women found the PHP intervention appealing, positively influencing their willingness to attend the sessions. However, a small minority of women exhibited hesitancy towards participation. Additionally, when these women did take part, their engagement in the group activities appeared limited or lacking in enthusiasm.

General practitioners' perspectives

Five semistructured interviews with GPs were conducted to understand their experiences working with BSA women with PND. The interviews also explored GPs' insight on the perceived feasibility, acceptability, and sustainability of the PHP in managing depression in primary care. The interviews were conducted in the North West (n = 3) and London (n = 2).

Four key themes from the interviews centred on: PND and its associated factors of stigma and culture, challenges experienced interacting with BSA women, increased support for BSA women and engaging BSA women though the ROSHNI-2 trial. The emerging themes from the interviews with the GPs reported below were similar to those conducted with the BSA women and the PHP facilitators, particularly related to the stigma of seeking help for PND.

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Theme 1: postnatal depression and its associated factors of stigma and culture

The majority of the GPs discussed the barriers they faced when interacting and consulting with BSA women who might have a diagnosis of PND. They described that women hesitated to approach primary care services due to the stigma of PND. They suggested that even though women may have symptoms that may represent a depressive illness, they did not openly express themselves and 'kept up with appearances' in front of the family because they did not want to get labelled:

> *It is very much common in South Asian women, but the stigma is there because as soon as you tell someone that you have mental instability and you need some help they get very scared about it because you know there is a stigma and they don't want to get labelled.*
>
> *GP NW-001*

The GP explained further the concerns that many patients might deny feeling depressed or have a lack of awareness of PND:

> *I have worked in different areas there are religious and culturally sensitive areas and supporting women from such backgrounds is very different because they are not very much open about it and as Asian women never come to us and say that I am feeling depressed, and I need your help. They do more with more somatic problems like my tongue is numb, my throat is numb, my hands are numb. They come with different issues they are related to more physical rather than psychological and they do not recognise that they are going through postnatal depression because there is a stigma behind it.*
>
> *GP NW-001*

One GP viewed PND from a cultural viewpoint where the expectation is that depression should be internalised and not disclosed:

> *I think it all comes down to the fact that you know what, in that culture, you've had baby, you're a mum, it's a happy occasion and if you're not feeling happy, there is something wrong, therefore, you hide it, you don't tell people, you cover it up. It's just the way the culture is.*
>
> *GP LO-004*

General practitioners suggested that women from South Asian backgrounds typically kept personal problems to themselves and did not take conversations and feelings out of the boundary of the house. GPs postulated that this stopped many women from actively seeking out support even if they were feeling low in mood:

> *There is also pressure not to disclose mental health problems and just to bear the problems and get on with things.*
>
> *GP LO-004*

The GP continued:

> *There are cultural issues as in they won't always bring certain things to the forefront, for example, postnatal depression. It's not a thing in this community to talk about and bring it up. So unless you've got high suspicion or somethings happened, it's not they are willing to bring forward.*
>
> *GP LO-004*

General practitioners suggested that the stigma of postnatal depression was even more pronounced for women who had immigrated from South Asian countries to the UK as compared to women of South Asian descent who were born and raised in the UK:

> *Very few women specially women who are moving from Pakistan they don't really actually connect here in the system but those girls who are born and bred here in this country they are slightly different they are a bit more open up.*
>
> *GP NW-001*

The interviews with the GPs suggest that the stigma associated with PND prevents BSA women from actively seeking help. The associated stigma acts as a hindrance; even though women might feel the need to seek professional help for depression, they hesitate and instead try to internalise their feelings.

Theme 2: challenges experienced interacting with British South Asian women

This theme highlights the unique challenges experienced by the GPs when interacting with women from South Asia or of South Asian descent. These include following an indirect versus a direct approach to build rapport, discomfort interacting with male GPs, not having enough psychologists from ethnic minority backgrounds, and missed appointments. As mentioned in the first theme, the GPs reported the initial barrier of fear of stigmatisation and labelling that BSA women faced while approaching primary care services. For those women who did approach the GP, the doctors faced several challenges in building rapport with them and setting an appointment for follow-up discussions.

Indirect versus direct approach

The first challenge was related to the number of follow-up appointments until the time the women finally opened up about depression and the need for help. GPs suggested that women often avoided talking about their own negative emotions, and most of the GP participants reported having to take an indirect rather than a direct approach when asking the women about their PND symptoms:

> *The biggest challenge is to engage them. They need help and when they come regularly to the surgery bringing their child in and if they are going through any psychological issues they will try linking to their somatic problems and they don't accept and agree that this is postnatal depression problem they don't accept the fact. They don't actually tell you openly that they are depressed.*
>
> *GP NW-001*

The GPs felt that culture had a strong influence on the way the women presented their problems and had discussions with their doctors:

> *Well it's interesting, the people from the Asian communities will present things in a different way, whereas people from the white community may come and tell you things much more straightforward.*
>
> *GP LO-005*

In recounting their experience of women not seeming to disclose their problems, GP participants said they followed an indirect approach to help the women feel comfortable and discuss their symptoms:

> *We have to be very careful and we cannot put anything on risk so we carefully phrase the question to find out they are feeling depressed like a routine check of the baby in 2 to 3 weeks' time and try to see how Mum is getting along.*
>
> *GP NW-002*

The indirect approach was also recommended by another GP, who commented:

> *Not to ask direct questions like are you feeling low or are you feeling depressed … like we ask the new baby has arrived how you are getting along with your sleep.*
>
> *GP NW-001*

Perspectives of male general practitioners

The male GPs interviewed felt that cultural perceptions about not disclosing feelings openly, especially in front of a male GP, made it difficult for the doctors to establish a connection with the women. This became even more difficult because most of the women were accompanied by their family members for the appointment and could not openly speak up about matters which were troubling them:

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> *But sometimes they don't make eye contact but making a full eye contact with a male GP is rare however it is difficult to get them engage sometimes we can sometimes we cannot or we get a translator even when they come along with any family member it can [be] difficult to speak and voice out. Also, difficult to talk about the domestic abuse and they are not comfortable to speak to a male GP or somebody else's presence.*
>
> *GP NW-002*

Lack of psychologists of ethnic minority backgrounds

General practitioner participants suggested that many BSA women did not approach primary care services because of the lack of availability of an adequate number of psychologists and translators from similar ethnic minority background in the healthcare system. This made the women lack enough confidence to share their feelings:

> *Well it's not PND alone … and one of the reasons is there is not enough psychologists with ethnic minority backgrounds and experience, trying to get a psychologist with that is challenging.*
>
> *GP LO-005*

Language was considered a barrier by a GP participant since the women at times were not able to make a GP appointment:

> *So sometimes ringing at the surgery and making appointment is difficult for them because there has to be somebody who can speak the language we don't have all the receptionists who speak their language. So I feel people who really need to see the GP there is a barrier to access the service due to language.*
>
> *GP NW-003*

Given the stigma of PND perceived by women and their families, the GPs faced challenges in building rapport with the women during the initial appointments due to the lack of acknowledgement by the women feeling depressed. The GPs took an indirect rather than a direct approach to enable the women to acknowledge their emotional difficulties and the need to actively seek counselling. However, there were several barriers faced by GPs in ensuring the BSA women accessed mental health services. These included not wanting to see a male GP, language barriers, the women's lack of education, insufficient translators, or lack of psychiatrists and mental health practitioners from an ethnic minority background.

Theme 3: increased support for British South Asian women

A key issue highlighted by GPs was that support seeking for postnatal mental health problems needed to be prioritised, since many BSA women struggled to accept that they were depressed due to the associated stigma and fear of being labelled. The GPs interviewed had a practice of not prescribing antidepressants straight away but rather advising follow-up appointments or meeting with the counsellor or community mental health team:

> *I try not to prescribe them straight away because some of the mums are breastfeeding and it is not good to prescribe such medicine. I don't actually start antidepressants straightaway and I tried to speak to them and discuss the issues they are going through that is the approach I take.*
>
> *GP NW-001*

However, GPs felt that the current assessment and support that was being offered was not optimal because of a lack of adequate follow-ups and not knowing whether the women did take up the counselling services that were offered to them:

> *I'm not aware of anything in the community that I can refer them to or any services. We can signpost them to midwives and health visitors. If they're antenatal, I know they've had a history we've flag it up to the midwives but we don't really have much input with the midwives. Again, I think its funding shortages, there is not much of a dialogue with health visitor.*
>
> *GP LO-004*

Some GP participants suggested group psychological intervention as an appropriate form of delivery for women to help them discuss more openly about PND and increase awareness and acceptance:

> *I think it (group therapy) works for everyone because women do not open up about their issues easily however if they are in a group they will be is they will get the support that helps them to discuss their issues and can talk to each other and make friends regarding baby and their other issues and can become more socialize.*
>
> *GP NW-001*

The GPs were also asked about their opinion on the place of delivery of group interventions for women. A GP participant felt that a community versus a formal hospital setting would be more appropriate:

> *I think community setting would be better because many time they have travel issues because if they don't drive they depend on someone to take them to that place so within the community it will be convenient plus travel cost is also an important part is here. So if they have to pay for a taxi and travel to a distant place they may probably would not go.*
>
> *GP NW-003*

Theme 4: engaging British South Asian women though the ROSHNI-2 trial

The GPs interviewed were supportive of the ROSHNI-2 trial as a possible way forward to engage with BSA women facing PND:

> *Yes, I have come across (patients) and have got some very positive experiences and I have not come across anyone who had negative experience of Roshni.*
>
> *GP NW-002*

The GP highlighted that the group therapy format of the ROSHNI-2 programme made it particularly appealing because it was reminiscent of the kind of peer support typically available in South Asian countries for women after the birth of their baby:

> *I think it would (work) because it draws cultural relations of peer support South Asia and community anyways back home which they expect to have access to. There is different mentality but it's about community raising children so extended family network and can break us down over the time and if the networks will be there and the support for the new participants. So, I think this new model works very well from the culture support perspective and peers support of the other participants who are going through the same situation.*
>
> *GP NW-002*

One GP participant reflected on initial reservations about whether the PHP intervention and the group therapy format would generate interest for participation but later realised the benefit of such a format:

> *I think when you first started I had my doubts about people getting involved with that but with time I realised there are a lot of people open to it because nothing much happens specific to BME patients so people are happy to get involved with this. So I think people just need to get used to the idea of groups and speaking to health professionals.*
>
> *GP LO-005*

General practitioners perceived that women's participation in the ROSHNI-2 trial had led to fewer *women with postnatal depression being seen in the practice:*

> *Yes, I think so and it has (ROSHNI-2 trial) deflected so many GPs appointments and so many issues that we probably would have taken ourselves as we had very positive feedback from Roshni. When I see patients bringing their children in and talk about their health and how their mental health is progressing, they provide such a positive feedback and are doing wonderful. So, in other ways it is impacting our workload and helping us to support these mums.*
>
> *GP NW-002*

Taking different approaches in the place of delivery and piloting the PHP intervention was discussed by GPs:

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> *GP would be one because that's where they're all going to. If it was highlighted in the community, and then you work alongside the GP units, it can be delivered in the community, it can be delivered one to one, it can be delivered as groups. If it's a community venue that everyone goes to, it can be done there.*
>
> *GP LO-004*

Discussion

The qualitative study for the main trial explores the experiences of BSA women participating in the PHP. Initially, participants had concerns about confidentiality and feared judgment from their community, but as they engaged with PHP, their outlooks loosened positively. They valued the therapeutic content and practical components like child care support and the opportunity to associate with other women facing similar challenges. PHP facilitators, mainly those with South Asian heritage, were drawn to the project due to its focus on maternal mental health and its potential to reduce stigma. Regardless of challenges like child care and family co-operation, participants and facilitators perceived the intervention as culturally sensitive and beneficial, posing valuable skills and support to improve mental health.

In addition, GPs supported the ROSHNI-2 trial as an encouraging approach to engaging BSA women facing postnatal depression. The group therapy arrangement of the ROSHNI-2 programme was viewed positively. The study highlights the potential of interventions like PHP to address mental health issues in this community effectively and reduce the stigma surrounding PND, offering hope for improved well-being among BSA women.

Chapter 8 Qualitative substudy

Remote delivery of the Positive Health Programme intervention during COVID-19 pandemic

Introduction

During the COVID-19 pandemic period, due to the social distancing rules, the research team sought ethical approval to continue the PHP intervention delivery remotely via video-conferencing platforms to ensure research continuity with participants. This substudy aimed to understand participants' views on the perceived feasibility, acceptability, and sustainability of the face-to-face versus remote delivery of the PHP intervention, and the PHP facilitator's perspectives on the mode of delivery of the PHP.

Method

Design

Semi-structured interviews with a subsample of trial participants and PHP facilitators were conducted to understand their perceived feasibility, acceptability, and sustainability of the face-to-face versus remote delivery of the PHP intervention.

Sampling and recruitment

We aimed to sample 15 participants. Participants were sampled purposively from two larger study sites – London and North West England. Trial participants were invited to include those who attended both face-to-face and video-conferencing sessions of the PHP intervention from different socioeconomic backgrounds, ages, and native languages. PHP facilitators were invited to include those who delivered both face-to-face and video-conferencing sessions of the PHP intervention.

Analysis

We used thematic analysis to identify key themes. Key themes were charted into the seven acceptability domains in the TFA. The seven components were used as a framework for analysis: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs and self-efficacy.

Results insight findings

A total of 10 trial participants and seven PHP facilitators took part in the study (*Table 33*). The findings informed the changes in the mode of delivery of the PHP sessions during the COVID-19 pandemic from face to face to a video-conferencing platform.

TABLE 33 Interview participants

Location	Trial participants	PHP facilitators
North West	8	5
London	2	2
Total	10	7

Findings

Affective attitude – how an individual feels about taking part in the intervention

Trial participants reflected on their feelings about engaging remotely in the PHP sessions and compared the experiences with face-to-face participation in earlier sessions. The responses shared by trial participants for the virtual delivery platform indicated that they had initial reservations about confidentiality and felt hesitant to speak about themselves in

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front of others in the household. They also felt that, compared to the virtual sessions, in the face-to-face format, they had a chance to enjoy some 'me-time' with other mothers who were going through similar experiences. They mentioned they missed the non-therapeutic elements, such as child care facilities, which were offered in the earlier sessions, refreshments, time away from daily routine, and the opportunity to meet with other women:

> *Firstly you get a change of environment, freedom of speech because when you are home the kids and husband is home so you cannot speak openly and secondly we need to attend the kids simultaneously as we are attending the sessions, and on top of it the most important thing is that when we see each other we have snack time or casual me time and we can go a little bit early or a little bit late, we have a play area for kids there and when the session finishes we can talk to each other or can have more interaction. So, I think face to face is helpful.*
>
> *Trial participant NW-033*

Elaborating further on the comparison between the two modes of delivery, trial participants appreciated the personalised connection built by seeing each other face to face and felt this was missing during the online sessions:

> *I would prefer face to face because the way you can talk face to face it's much better you can be more friendly you can like when you're in front of somebody its different to when you're over the phone like you cannot see each other's faces that much and you can't see the person you are talking to properly so I would prefer face to face you can have a better connection face to face.*
>
> *Trial participant NW-033*

Burden – the perceived amount of effort that is required to participate in the intervention

Due to the online format of the intervention, the usual support service, such as child care, was unavailable during the session to the trial participants. Many participants found it challenging to attend these sessions and the other household responsibilities. As a result, some of them struggled to attend the sessions with complete attention and found it challenging to fully engage where they could learn new skills effectively:

> *I think it is like when we are attending the online sessions it happened to me like I was sometimes cooking while attending the sessions and which is sometimes very distracting and sometimes kids used to attack me and it was only that time which was my me time when I used to attend the class however there was a lot of other stuff going around which was unavoidable and what other participants also said about it that it was difficult at times to attend the sessions with complete concentration. So, I think online sessions have a lot of distraction.*
>
> *Trial participant NW-05*

The trial participants reflected on how they felt about engaging remotely in PHP sessions and reported that in face-to-face sessions, they could express themselves better and get a change of environment:

> *The face to face is better actually, because in a face-to-face session you were able to leave the house and could go out of the house in a different environment and speak with freedom and can express your problem in a better way.*
>
> *Trial participant LO-04*

The PHP facilitators expressed their concern as well related to the constant challenge of keeping the participants engaged for up to 90 minutes when many of the mothers were multitasking, such as looking after the baby or doing some household chores while attending the sessions. Though the facilitators maintained the protocol by sending reminders to the participants for these sessions regularly, however, it appeared a burden:

> *As the sessions are delivered remotely it is difficult to keep the attention of the mums on the session for a longer time and is very challenging to engage the mum while she is taking care of the baby. So it is difficult to suggest anything, however, most of the mums attended these sessions regularly.*
>
> *PHP facilitator NW-047*

The majority of the PHP facilitators who delivered the virtual intervention sessions expressed their concerns in terms of the technical aspects of having to shift to virtual sessions since they felt the trial participants were not very comfortable with using technology:

> *I would not say virtual sessions are better than face to face because we had a couple of mums who did not know how to go about managing Google hangout joining the conversation knowing that they have to mute not every mother was equipped technology-wise.*
>
> *PHP facilitator NW-011*

Likewise, most of the PHP facilitators preferred face-to-face sessions over the remote delivery of the PHP sessions for a number of reasons, such as lag in response time after a task because the trial participants were not there physically, and they had to wait for their responses as well as persistent connectivity problems:

> *There is a lot of difference like online we say something and then wait for the response than we need to be prepared for things that may go wrong like internet issue or connection issues.*
>
> *PHP facilitator NW-032*

Some of the PHP facilitators, however, acknowledged that the remote sessions were useful and stated that such sessions facilitated participation for trial participants who were unable to travel or were bound to their house due to their responsibilities. They felt that because of the online nature of the sessions, participation became possible for them. One of the trial participants mentioned:

> *I can say that remote one is good in a way that if you do not have time and cannot go out of the house you can still attend the session as when the baby is young you need to arrange so many things before you move out of the house so I think remote delivery is better than face to face.*
>
> *Trial participant NW-006*

The views of the trial participants and the PHP facilitators reflect that even though the study helped the trial participants engage during the lockdown, the virtual sessions were not always easy to manage due to internet connectivity, initial hesitation in using technology, and multitasking. There was a clear preference for attending face-to-face sessions over remote sessions.

Ethicality – the extent to which the intervention has a good fit with an individual's value system

Trial participants were positive about receiving PHP intervention and considered it as an important step forward to address postnatal depression. Most trial participants agreed that discussion about mental health in South Asian communities is challenging, as it is perceived as a stigma. Some of the participants also explained that the community usually has no awareness about postnatal depression and simply disregards its existence or labels a woman facing postnatal depression as a mad or psychotic person (NW-005). The participants considered PHP to have a good fit with their value system:

> *I think we should have more open seminars and more open sessions or open talks about this problem like Roshni-2 is doing a research-based work or session. So I believe there should be more studies like that which is more open to mums moreover, there is a language barrier there is an approach barrier and education barrier so I think the best way is that say for example I have been part of the group and if I have been by one of the Roshni members that we need more mums I will spread the word out and will assist in getting the help to the mums who need it.*
>
> *Trial participant NW-033*

However, there were a few confidentiality issues raised in conducting the remote sessions. As the term depression is stigmatised in the BSA community, some of the trial participants felt it was a great challenge to speak openly and maintain confidentiality during the remote sessions:

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> *I did not feel comfortable especially when I used to discuss my in-laws in front of my husband. It's not that he does not understand but I used to feel bad and I avoid talking about his family and he understands, and he knows what I have gone through because of them and I think it is kind of insensitive to speak about his family in front of him so that was the only part I think.*
>
> *Trial participant NW-005*

The PHP facilitators reported that though postnatal depression is a stigma in BSA communities, the content of the intervention supported the value system of the mothers and helped them to connect more effectively with their values:

> *I think culturally adapted therapies for mental health are beneficial. The reason is that there are a few times when we speak to mums they open and say that the reason I am speaking to you is that you are speaking my language and this intervention is doing the same. It gives you a sense of understanding and not being judged. So, I think this kind of intervention is very important and further narrows it down to a certain community to be able to interact and learn their needs.*
>
> *PHP facilitator NW-032*

The PHP facilitators and the trial participants appreciated the PHP since it was culturally adapted and prioritised all the needs desirable to address the cultural norms of the South Asian community.

Intervention coherence – the extent to which the participant understands the intervention, and how the intervention works

Before the intervention began, participating mothers, in both face-to-face and online formats, perceived PHP as something that would address their low mood and/or enable them to solve problems:

> *I found every session very enlightening by listening to everyone's experience. It was just nice talking to other people. I was able to explore myself and I said to myself that I can do this. These sessions empowered me in some way which I liked that all scenarios should have been about, and I believe life is all about empowering each other.*
>
> *Trial participant NW-005*

The PHP facilitators emphasized that because the PHP sessions, both face to face and online, were culturally adapted, it helped address the emotional needs of the mothers as well and to take better care of themselves:

> *I would say these sessions were helping because one, it deals with the issue of isolation providing them with group support secondly who neglected themselves can care about themselves, thirdly I have seen that CBT works. Cognitive therapy was culturally adapted and was delivered as a positive health program in ROSHNI.*
>
> *PHP facilitator NW-011*

Opportunity costs – the extent to which benefits, profits, or values must be given up engaging in an intervention

This construct reports the compromises a trial participant had to make to participate in the intervention. Some of the trial participants reported that due to the remote sessions, they were unable to participate with complete attention since they were involved in multiple other activities at home, along with attending the online sessions. They missed the earlier, carefree environment of the face-to-face sessions and felt they had to compromise on their freedom and liberty to have open discussions:

> *Firstly you get a change of environment, freedom of speech because when you are home the kids and husband is home so you cannot speak openly and secondly we need to attend to the kids simultaneously as we are attending the sessions and on top of it the most important thing is that when we see each other we have snack time or casual me time and we can go a little bit early or a little bit late, we have a play area for kids there and when the session finishes we can talk to each other or can have more interaction.*
>
> *Trial participant NW-033*

Positive Health Programme facilitators indicated that due to the remote delivery of the sessions, the intervention did not offer the opportunity of having 'me time' for the mothers that used to be provided to them in the face-to-face sessions. With additional supports, such as child care and snack time; however, this did not impact the attendance to the remote sessions.

Perceived effectiveness – the extent to which the intervention is perceived as likely to achieve (or have achieved) its purpose

This construct is interpreted as the extent to which the intervention will likely attain its aim. This becomes even more important to understand during the present times when the mode of delivery is remote via virtual sessions:

> *It has provided me with the right direction the right answers to the questions that we were thinking about on our own and speaking to other mums. I think if I would not be invited to that group, I would have gone for counselling, however, due to COVID and lockdown I would be stuck at home but being home, speaking online, and having that support and interaction was helpful for me. If I would not be invited to the group, I do not think I would be the same person I am today.*
>
> *Trial participant NW-033*

Most of the women acknowledged the effectiveness of these sessions and how they improved their low mood and made them feel confident in improving their skills. The statements that were recorded were 'I started feeling that I am worthy' (NW-005):

> *Though it was not providing the complete support that I was looking for it was providing the partial support like the emotional support that I was looking for and learning from the experience of the other mums and listening to the doctor as well. It supported me in a way that I was able to socialize, and I thought it is a great opportunity to see and talk to new people and it was kind of a blessing in disguise for me.*
>
> *Trial participant NW-005*

The PHP facilitators also agreed that even though the virtual sessions may not be the best way to deliver the sessions, given the times and lack of alternatives, they were helpful to the trial participants by enhancing their online social networks and boosting their confidence and self-esteem:

> *Even though the session was online, but they were able to connect and keep in touch with each other. So, all in all, no matter due to lockdown they are all connected, and we had a very positive response from the mums.*
>
> *PHP facilitator NW-032*

Self-efficacy – that participant's confidence that they can perform the behaviours required to participate in the intervention

Trial participants, in both face-to-face and online formats, felt empowered by learning new skills, such as time management, learning to say no, and making more time for themselves. They also reported improved communication skills:

> *My communication skills were poor previously and through these sessions, I improved my communication skills I speak very little and take time to get comfortable with others, however, these sessions increased my confidence and helped me to improve my communication skills.*
>
> *Trial participant NW-047*

However, it was noted by trial participants that they could not express themselves openly and discuss their issues freely around family members in a shared household, especially when the conversation was about a particular family member. Although the PHP facilitators made efforts to maintain confidentiality by providing trial participants with headphones, some of the participants felt uncomfortable engaging in lengthy conversations due to the proximity of the family members:

> *I generally had my mother-in-law around me sometimes, so I did not talk much.*
>
> *Trial participant NW-033*

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The PHP facilitators played a vital role in engaging with the trial participants during the sessions and helping maintain confidentiality. Trial participants were given options of putting down their feelings in the chat box if someone was around and later having a follow-up after the virtual session. As one of the PHP facilitators explained:

> *We said to the mums that if they could not talk or could not be honest about something or felt uncomfortable or if there is someone in the room, they could just put a comment in the comments box and so they knew how to do that, so some mums did type in that I cannot talk now and we were all aware of that and we tried to follow them up later through the phone call to check on them.*
>
> *PHP facilitator NW-004*

Positive Health Programme facilitators reported overall satisfaction and confidence in delivering the sessions remotely. Initially, the PHP facilitators were sceptical about the remote sessions, but with adequate training, they felt prepared to deliver the sessions effectively:

> *I would say there were lots of issues and we felt at the beginning and it was quite challenging there was a bit of anxiety, there was a bit of uncertainty, there was a bit of apprehension that how would the sessions are going to turn out. And whether the Internet is going to work or not and how mums are going to deal with it. However, the results were quite surprising in the first session we had six mums in the second session we had eight mums and by the end of the third session, the mum had their own WhatsApp group.*
>
> *PHP facilitator NW-011*

Furthermore, adequate training before the sessions helped them better understand the programme, especially in the new format of remote delivery:

> *Our trial manager provided us with all the due information and prepared the slides on PowerPoint that assisted in understanding the sessions we were delivering. We were provided with a zoom session to practice a trial session with our co-facilitators to know how we can manage things to work.*
>
> *PHP facilitator NW-047*

Discussion

The findings highlight the multifaceted interplay of factors shaping participants' experiences in the PHP programme. Participants had mixed feelings about engaging in remote PHP sessions compared to face-to-face ones. They articulated initial uncertainties about confidentiality, the lack of personal connections, and the non-therapeutic elements that face-to-face sessions provided, such as child care and socialisation. The burden of contributing remotely was evident as participants grappled to balance household responsibilities, child care, and focus during the sessions. Technical challenges and connectivity issues added to the difficulties of remote participation.

On the other hand, while some participants faced challenges sustaining open discussions due to distractions at home, others valued the convenience and accessibility of remote sessions. Regardless of these challenges, participants and PHP facilitators acknowledged the intervention's positive impact on participants' mental health, self-esteem, and communication skills. Satisfactory training helped PHP facilitators familiarise themselves with remote delivery, improving the programme's overall effectiveness.

Chapter 9 Discussion

Postnatal depression is a substantial public health concern, affecting approximately 17% of mothers globally.[9] This area of research has been prioritised by the NIHR across all programmes in accordance with the 'Best Research for Best NHS' guidance by the NIHR.[114] The ROSHNI-2 trial is the first large-scale evaluation has been undertaken to examine the clinical and cost-effectiveness of a culturally adapted group psychological intervention for postnatal depression in ethnic minorities living in high-income countries. We determined the clinical and cost-effectiveness of the PHP in a multicentre RCT across England. The main findings of the ROSHNI-2 study will now be discussed in relation to (1) the estimates of the clinical effectiveness, (2) estimates of cost-effectiveness and (3) qualitative examination of the acceptability and feasibility of the PHP group-based intervention.

Trial-based estimate of the clinical effectiveness of the Positive Health Programme for postnatal depression in British South Asian women

The RCT compared a culturally adapted CBT-based intervention, the PHP-plus-TAU, with TAU for BSA women with PND. The participants met the DSM-5 criteria for depression, confirmed by the SCID-5. The primary outcome assessment was at 4 months and subsequent follow-up assessments (secondary outcomes) conducted at 12 months after randomisation. The SHAPER-PND trial looked at a community singing intervention for PND, follow-up was conducted at week 6 (mid-intervention), week 10 (end of intervention), week 20 and week 36.[115]A large cohort study, the Avon Longitudinal Study of Parents and Children, reported measurement of PND on a continuum of symptoms rather than a dichotomous diagnosis of PND.[116]

The findings of the study illustrate the evidence for its effectiveness in primary care to deliver a group psychological intervention PHP.[54] The trial also addressed the need for an approach which takes into account cultural awareness while developing and delivering interventions for women in the UK from ethnic minority backgrounds; this is important considering the high rates of maternal depression in this group of women.[58,117] In addition, the ROSHNI-2 trial aimed to address the limitations of earlier trials which mainly consisted of small, non-representative sample size, high attrition and short follow-up,[118] making this trial the first major investigation with ethnic minority women living in high-income countries.

Primary outcome

A total of *n* = 732 participants were recruited across 4 study centres in the UK and were randomised to one of the trial arms. The primary outcome being recovery from PND. Participants were considered recovered if they had a HRDS score of 7 or less. The results indicate that at 4 months (primary end point), half of the participants in the PHP group (49%) recovered, compared to 37% in the TAU group. These improvements were smaller than the anticipated clinically meaningful ARR of 15% (albeit with a large degree of uncertainty and a 95% CI that includes this). However, after adjusting for centre, severity of depression, and education at baseline, the odds of achieving recovery in the PHP group were nearly twice as high compared to the TAU group (OR 1.97, 95% CI 1.26 to 3.10). Applying this adjusted estimate to a population recovery rate of 38% results in an ARR of 0.17% and a NNT of 6; meaning that, for every six patients who are treated, one will recover. By 12 months, the difference in recovery rates became statistically non-significant, with the TAU group also improving and recovering.

Secondary outcomes

On analysis of the secondary outcome measures, one of the secondary outcomes was related to a treatment response on the HDRS measure, which showed a reduction of 50% or more from the baseline score on the HDRS. In the treatment (PHP) group, 56% of the patients experienced a treatment response compared to 40% of the control (TAU) group. At 12 months, the treatment response was 61% (PHP group) and 58% for the control (TAU) group.

For depression symptom severity, measured by the PHQ-9 total scores, the treatment group had a significantly improved total scores at 4 months (β = -2.05, 95% CI -3.18 to -0.92); however, at 12 months there was no meaningful difference (consistent with the recovery at 12 months). At 4 months, the treatment group also scored significantly lower

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on anxiety in comparison to the control group (β = -1.45, 95% CI −2.66 to −0.25) but again this was not different at 12 months. In addition, the parenting competence measure, although there was found to be no significant difference in parenting sense of competence scores at 4 months between groups, However, at 12 months the intervention (PHP) group had a higher score, on average by 2.32 points (95% CI 1.10 to 5.54), indicating a significantly higher sense of competence than the control group. There was no significant difference in social functioning between groups at 4 or 12 months.

Cost-effectiveness of the Positive Health Programme

The PHP implementation for PND was estimated to cost an average of £408 per participant. The PHP intervention was found to lead to higher incremental costs and QALYs gains among South Asian women. The intention-to-treat analysis revealed that the PHP intervention costs £22,198 per QALY, with a probability of cost-effectiveness of 56% at the willingness to pay of £25,000. A disaggregated analysis by the number of completed PHP sessions, revealed that four or fewer completed sessions have no incremental effects on QALYs. Participation in 5–8 sessions of the PHP resulted in a 0.04 increase in QALYs per person compared with the control arm, and participation in 9–12 sessions resulted in a 0.05 increase in QALYs per person. Participation in 5–8 sessions was relatively cost-effective compared with 9–12 sessions. For those who attended 5–8 sessions, PHP intervention costs £9040 per QALY gained, with a probability of cost-effectiveness of 71% at the willingness to pay of £15,000 and associated mean net monetary benefits of £255.

We believe that the cost-effectiveness estimates given in this report are conservative and provide the upper bound of costs per QALY gained. Healthcare usage for some conditions is hard to change in the shorter term as in the current case. For example, the data show that most secondary care uses were less likely due to the participants' mental health. After excluding secondary care from the cost calculations, the intention-to-treat analysis revealed that the PHP intervention costs £16,961 per QALY. The probability of cost-effectiveness is 59% at the willingness to pay of £20,000. Second, the primary and secondary care costs were higher among the PHP arm at the baseline. Similarly, the PHP intervention involved developing assertiveness skills and helping participants to build confidence, improving communication, and overcoming social isolation by creating new relationship and fostering new social networks. This might lead to overcoming the fear of stigma, leading to more healthcare use and self-reporting, at least in the shorter term. Finally, children's centres were costed at the rent charged by community centres, which may charge higher rates in some instances. Note also that the participants were paid £10 per session. However, that amount was not included in the economic valuation, as the economic evaluation used a healthcare perspective, and the healthcare system in the UK does not cover such costs in practice.

Stevenson *et al.*[119] combined clinical-effectiveness results from Honey *et al.*[120] and data from PoNDER trial to estimate the cost-effectiveness of group CBT for PND in the UK. The mean cost per QALY from the stochastic analysis was estimated to be £36,062; however, there was considerable uncertainty around this value. Camacho and Shields[121] report seven studies, excluding Stevenson *et al.*,[119] assessing the cost-effectiveness of interventions for prevention, treatment, or screening and treatment of postnatal depression. These studies assess different forms of treatments: access to psychiatric day hospitals, counselling and support delivered by trained health visitors, cognitive–behavioural therapy, collaborative care for depression, psychosis in partnership with a psychiatrist, etc. In these studies, the interventions ranged from dominant (rare) to ones costing more than £30,000 in 2015. Similarly, the cost per recovery ranged from low to as high as £56,865. Thus, the PHP intervention's QALY gains and cost per QALY appear to lie within the middle (if not below) of the gains and cost of interventions reported in the existing literature.

Need for culturally adapted psychological interventions

The ROSHNI-2 study was developed based on extensive previous research and builds on an earlier PhD study by Khan *et al.*[54] and ROSHNI-D study[26] and several systematic reviews,[76] which call attention to the immediate need for well-researched studies that can answer crucial questions about PND and the need for culturally adapted psychological interventions. The gaps in research, as reported in *Chapter 1*, include:

- The limited number of well-planned RCTs in the UK for ethnic minorities.

- The dearth of up-to-date studies examining the effectiveness of culturally adapted interventions specifically for the BSA population.
- The need to improve health outcomes of South Asian women in the UK facing PND by assessing the effectiveness of NICE recommended psychological interventions.
- Limited evidence and evaluation from the current research base related to economic costs culturally adapted interventions.

The present study is an important step to improving current understanding on conducting research with a hard-to-engage group, with an elevated risk of PND. The findings of the study further highlight the experiences and acceptability of a culturally adapted intervention (PHP) by the South Asian population in the UK, which is also the largest ethnic minority group. The results are largely comparable with clinical trials on postnatal depression. An important point to be considered while discussing the results with previous research findings is that there are few available studies of trials with ethnic minority women as a point of comparison.

The challenges of delivering care differently

This study highlights the compelling evidence that delivering group therapy within a health service setting offers efficiencies over usual care. Similarly, a meta-analysis focusing on community studies demonstrated the effectiveness of psychological interventions, deliverable in primary care, at reducing symptomatology of PND.[122] In addition, a 2013 meta-analysis of 28 trials involving close to 17,000 pregnant women and new mothers (< 6 weeks post partum) reported that women were less likely to progress to postpartum depression if they received the psychosocial intervention or psychological therapy compared with usual care.[123] The NICE guidelines[51] recommend CBT and IPT as the first-line management approach for PND. The PHP intervention evaluated in the ROSHNI-2 trial is modelled on CBT principles. The psychological intervention was culturally adapted for use with BSA women through the use of cultural adaptation methodologies and previous research.[26,53,66,104] A recent network meta-analysis for different subtypes of psychotherapies points to recurring positive results about CBT, and points out whether done as a combination or on a standalone basis, it generates a more enduring response than the usual treatment for major depression.[124]

Furthermore, the ROSHNI-2 trial showed benefits related to the primary outcome measure, recovery from PND, and other secondary outcomes, including improvements in anxiety symptoms. These improvements were seen at 4 months and continued by the PHP group; however, at 12 months there were no differences between the groups. In the short term, the greatest benefits were apparent for the PHP group, which is in line with research on achieving a treatment response to depression[125] and predictors of variability of depressive symptoms in the long-term in long-term trajectories of depressive symptoms, including, among others, being a woman, a mother, having a low income/education, and belonging to a non-white race.[125] The important finding is that the improvement in depression in the PHP group was sustained up to 12 months after randomisation.

Compliance analysis results indicated that that three-quarters of the participants met compliance to treatment attendance (n = 246) (a participant attending at least 1 therapy session), indicating that most participants engaged well in the PHP intervention. Moreover, participants also completed, on average, 8.94 sessions, with findings similar to the ROSHNI-D[26] that mother who attended 1 session, were likely to continue to engage with the PHP group. Forde *et al.*[113] reported that for reducing depression, attending 6–8 sessions offers more benefits than attending 1 –5 sessions. The high level of engagement in this trial could be due to several reasons despite the barriers highlighted by trial participants, such as the stigma attached to poor mental health in the South Asian community. Qualitative evaluation of the PHP interventions suggests possible reasons for the success of PHP, and these include the targeted community engagement events, which were conducted across the study period to increase awareness, in addition to active meaningful PPIE for the study and public-facing materials. The intervention was presented as a life-skills training programme rather than therapy. For engagement with the wider family the focus was more on the child rather than the mother. The internal pilot provided us the opportunity to increase awareness about the benefits of PHP at the different study sites. The intervention was culturally adapted, which could have influenced its positive take-up and effectiveness. The importance of cultural adaptation of interventions has been confirmed by various reviews, highlighting that culturally adapted psychological interventions provide better outcomes compared to interventions that are not culturally adapted.[126]

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Acceptability of the Positive Health Programme

Overall, the qualitative data suggest the acceptability of the PHP from perspectives of trial participants, PHP facilitators and GPs. Trial participants and PHP facilitators expressed satisfaction with session content being culturally acceptable, with the frequency and format of the PHP intervention delivered and considered as relevant to their culture.

Several processes observed in the qualitative study can explain the reduction in depression and anxiety observed in the trial, particularly at the 4-month follow-up. The findings support previous research,[127–129] which suggests that participation and interaction in a group provides participants with a forum to interact with others and in the process develop skills which can help cope with low mood and move forward. The trial participants reported that PHP group members provided feedback and supported each other during and outside the group session by staying in touch and building their social network. The group setting provided participants with a sense of support through shared understanding and acceptance. It is plausible that increased social relations and networks may directly affect depression.[130]

Trial participants described perceived benefits of developing new skills to improve their well-being; leading to being more confident and increase in self-esteem.[131] This could explain the better observed outcomes in the trial at the 4-month follow-up period. Therefore, it is also reasonable to consider that increased social support may have mitigated the impact of social stressors, such as maladaptive coping and stigma.

The findings support previous research,[132] which proposes benefits of participation in a trial, including reduction in associated stigma and improved care for mental health difficulties that participation in a trial can help reduce stigma and improve care for mental health difficulties, such as depression and anxiety. Before starting the PHP intervention, participants were concerned about stigma associated with their experience of PND and the concerns about community 'grapevine'. However, the women and PHP facilitators reported that women gained confidence and developed greater assertiveness skills after the PHP intervention. This resulted in improvement in their relationships with others and making time for self-care. Women reported that they better understood their feelings and more self-awareness. They were able to implement newly learnt coping strategies and engaging in pleasant activities suggested by the facilitator. However, for some trial participants, low mood persisted at the end of intervention and the women suggested that there should be booster sessions. PHP facilitators also noted that the engagement in the intervention was dependent on the level of support from family members and trial participants' intent to address their own problems.

All participants clearly described the value of assisting BSA women in engaging them in activities that they find enjoyable and meaningful, and which resonates with their cultural experiences. Awareness and action to support and improve their low mood and depression are important as it is fundamental to a women's well-being.[18,127] Yet, engagement in existing support services and the lack of culturally sensitive services were identified by participants as one of their major unmet needs.[16] Therefore, as an intervention, PHP made sense to trial participants and PHP facilitators. This is relevant to implementation; according to the TFA,[105] one of the thresholds for positive implementation of a new intervention is to be 'coherent' or make sense to those involved in delivering and receiving the intervention. Implementation literature suggests strategies should focus on known barriers to behaviour or practice change.[133] Therefore, therapists' training in the use of PHP extends to understanding the target population and the cultural barriers associated with stigma and shame, concerns about referral to health professionals, and exploring approaches to enhance the relevance and acceptability of PHP for families and broader engagement with South Asian communities. Implementation of new interventions such as PHP also necessitates health professionals to understand what the intervention involves in sufficient detail to allow the impartial presentation of information, ensuring BSA women and their family members make an informed decision about participation.[134]

The South Asian cultural focus of the PHP intervention and group therapy approach made it particularly appealing. The GPs were hopeful about the long-term benefits of the intervention, with the PHP potentially bridging the gap that GPs describe in the support and management of BSA women in primary care. Continuing with community engagement and awareness, and 'success stories' for PHP and tailoring messages for different stakeholder groups will therefore be important in the take up of the PHP intervention.

Impact of COVID-19

The COVID-19 extension qualitative work aimed to understand the acceptability of the PHP, delivered during the COVID-19 pandemic, from the perspective of South Asian mothers in the UK with PND. We also examined the experiences of community facilitators and therapists in the planning and implementation of the remote therapy sessions and the differences they felt in delivering the remote versus in-person sessions. The women were already attending the PHP sessions before the nationwide lockdown and were in a unique position to compare the advantages and disadvantages of the online sessions. The overall results provide rich learning and include lessons on how best to optimise services for remote therapy, particularly for those groups which are hard to reach.

In-depth interviews with participants and therapists indicated that in-person format was a clear preference as a mode of delivery of the PHP intervention when compared with the online sessions. Women had some reservations in expressing their feelings effectively due to sometimes family members being around. Similar conclusions in research on limitations of video-based/online interventions and remote care for mental health also advocate the distinctiveness of face-to-face sessions over remote care, particularly related to confidential conversations.[134]

Another factor that had an impact on the quality of engagement in remote delivery sessions was multi-tasking. Due to the lockdown some women were looking after the children and carrying out household chores alongside attending the intervention. Other barriers in delivery of the online sessions included unstable internet connection, and initial hesitation for use of technology for some of the participants. Comfort in using the technological platform can sometimes underpin the successful delivery of online therapy sessions.[135] However, participants frequently reported difficulties with the inadequate technological arrangement and poor internet connectivity issues, such as speed and strength of network bandwidths, thereby creating issues with delivery of a smooth session.

Many participants valued the flexibility provided by remote delivery of the sessions, particularly for those who felt that household responsibilities had earlier prevented them from attending the face-to-face sessions. They felt that the online format, even though not ideal, helped them navigate the difficult times during the lockdown, supported their personal development, and provided a network to the women by helping them share experiences and get advice in a non-judgmental setting. Majority of the facilitators who delivered the online intervention were of South Asian background with bilingual skills, accommodating the diverse needs of the participants, which was appreciated by the participants. Some reservations, as expressed by the facilitators for the online sessions, also included not having a 'me time' for the women which was there in the face-to-face sessions, like child-care facility and snack time where women used to get a chance to socialise. Having a meal/snack together, especially in the Asian culture, is considered as a meaningful activity which promotes social interaction.[136] However, this did not affect the attendance of the participants. Social cognitive theories like the theory of planned behaviour,[137] commonly used to understand dietary behaviour in health psychology, further explain how eating together evokes positive emotions of togetherness in people.

The qualitative study suggested that the PHP intervention was perceived as feasible and acceptable by the trial participants, PHP facilitators and GPs' perspectives. The perceived benefits of increased social networks and behavioural activation could have been the therapeutic factor, engaging in activities that participants found enjoyable and meaningful and discussion and information that resonates with their cultural experience. Awareness and action to support and improve their low mood and depression were necessary to increase participants' understanding and utilise coping skills where needed. In addition, culturally adapted PHP intervention content enabled intervention delivery and was positively received by the South Asian population. The qualitative data helped in a better understanding of the context and expanded the learnings from the trial outcome of how PHP contributed to reducing depression.

Strengths and limitations

This study is unique, given the stigma surrounding mental health in South Asian communities. The study has demonstrated a high level of recruitment and retention [approached *n* = 9135, screened *n* = 4319, randomised *n* = 732, 4 months follow-up *n* = 578 (79%)]. The ROSHNI-2 trial is a crucial step forward in trial knowledge and working with hard to engage groups. Learnings and knowledge gained from the trial will assist in further formulating and modifying current guidelines related to PND, especially for ethnic minorities in the UK. The recruitment of ROSHNI-D and now ROSHNI-2 highlight the team's ability to engage with a 'hard-to-reach' community. The key adaptations made to the

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PHP intervention are the use of culturally appropriate language and intervention resources. Care was taken to ensure that all the study materials and final delivery of the intervention was made in Urdu, Bengali, Gujarati, Punjabi, Hindi and Tamil languages, and in an easy-to-use manner via relatable stories to apply the principles of CBT. To our knowledge, this is the first RCT in the UK working across five different languages.

As the results state, recovery from PND is more rapid in the PHP group immediately post intervention; however, there is also recovery in the TAU group over the 12-month period. This could potentially be explained partly as a result of the additional methods employed by the study team for recruitment and retention of participants. For example, engagement events were held in which workshops were focused on increasing awareness and psychoeducation in this study population. It was important for the team to do this level of community engagement in order to increase research participation in this community and tackle stigma about maternal mental health and also build trust in services and research involvement. Further research is also needed to explore the role of brief follow-up contact in this study population.

A limitation of the study was the relatively high level of missing data: overall, 23% of participants had missing data for the primary outcome. There was no association between baseline characteristics and whether or not a participant had missing outcome data, therefore we did not have evidence that excluding those with missing data biased the results. In addition, the results were robust to a sensitivity analysis that assumed participants with missing data had not recovered. Regardless of bias, while a statistically significant effect was detected, the high level of missingness limits the precision in the final estimate. A further limitation was that we report only a relative measure of effectiveness, whereas an absolute measure of change – for example, the NNT – may be a more appropriate measure for assessing the intervention's public health benefit. The challenge in calculating this statistic is that models used to estimate this tend to be more difficult to fit, and doing this should be the focus of future work.

Introducing different deviations to the multiply imputed data in the sensitivity analysis revealed that such deviations bring minute changes in the costs and effects estimates, and the primary analysis's results still hold.

This trial also makes a unique contribution to the limited scientific literature examining the processes and development of culturally adapted psychological interventions, with a focus on PND, for ethnic minority women.

Mixed methods was a particular strength of this trial and it allowed us to gather both quantitative and qualitative data, thereby adding perspectives to the research questions. Interviews conducted with the participating mothers, PHP facilitators and GPs enabled exploration in detail of culturally adapted intervention. There is typically a paucity of usage of theory and frameworks in perinatal health research,[138] therefore, employing the thematic framework of acceptability is an important contribution to the literature. The remotely delivered PHP intervention during the pandemic provided an online platform for participating women during the lockdown when ongoing restrictions made it difficult to carry on with the face-to-face sessions. It provided a sense of continuity for the women who were engaging well with the PHP sessions earlier and a sense of support for those participants who had joined for the first time.

The ROSHNI-2 trial also provided estimates of the cost-effectiveness of the intervention, helping plan future services particularly for excluded groups. This is important as there are few cost-effectiveness analyses of culturally adapted interventions for PND. A possible limitation of this trial is that the sample of the study includes only BSA women; hence, the study findings cannot be generalized to the other ethnic minority groups. In addition, the geographical proximity of many of the participants can lead to the assumption that they were acquainted with each other and could share their experiences of participation in the intervention as well. Potential contamination can, therefore, be expected.

In an attempt to be inclusive, we did not limit the sample to only first-time mothers and included experienced mothers as well. The challenges faced by first-time mothers can be very different from those experienced mothers, which is a limitation we did not consider. Further information on social deprivation, poverty, and family composition are also likely to impact mothers' experiences. The experiences of different generations of BSA women are also likely to be different. Finally, concerning the cost-effectiveness analysis, the current analysis did not explore recall bias, which may have been introduced due to collecting data using self-report methods at 4- and 12-month duration. Additionally, the economic evaluation used only a healthcare perspective and does not cover the cost of medication.

Chapter 10 Conclusions and future research recommendations

The study has been successful in initiating a multidisciplinary dialogue on a wide scale across the UK and addressing the urgent need for a culturally adapted model of engagement and delivery while working with 'hard-to-reach' communities. Overall, the non-specialist delivered group-based PHP was effective in treating PND among BSA women in the short term. Integrating and implementing PHP group sessions into existing health systems was feasible and acceptable. The ethnic minorities community that is often considered 'hard to reach' has been expressed by one of the community partners as 'easy to ignore' since services are not tailoring their approach and the process of mapping communities and cultural engagement is limited. The results suggest some form of maintenance contact and additional maintenance treatment to further improve recovery in the form of additional PHP sessions should form the basis of future research with a longer-term follow-up. The creative methods of recruitment and engagement and dedication to working with the community to enhance participation in research can serve as a best practice example for recruitment in future studies.[139]

The benefits seen in the primary outcome were sustained at 12-month assessment in the PHP group; however, there was no significant difference with improvement in the TAU group. There is ample clinical trial evidence that this is a typical longer-term outcome, which is a well evidenced but rarely discussed limitation of depression treatment evaluations.[125,140] The value of benefits of faster recovery of depression even in the short term cannot be underestimated for the PHP group participants, and arguably, crucially for the baby and possibly also other family members. Whether it further improves the longer-term course and trajectory of depression is not well understood; a significant proportion of cases of depression have a long past history of depressive symptoms and a poor outcome with either fluctuating or continuous trajectories.[125] Funders and researchers should be examining this and reconsidering research priorities for improving future years lived free of depression and though important, not only just the short-term outcomes that are almost ubiquitous in treatment evaluation research.[141,142]

The present findings suggest that a form of maintenance contact and, where indicated, further treatment, possibly in the form of additional PHP sessions, should be the focus of future research intervention development and evaluation, importantly with much longer-term outcome follow-ups as is accepted without question in cancer trials. We are currently carrying out a test of remote brief PHP intervention, which may be a cost-effective intervention for sustained long-term impact.

We are also exploring adaptation for treating PND in British mothers of African/Caribbean heritage. The model of cultural engagement and delivery that has been learnt from ROSHNI-2 can be applied to other ethnic groups that require a culturally sensitive approach. Feedback from ROSHNI-2 participants highlighted the need for future interventions addressing interpersonal violence (IPV) using a format similar to the PHP.

Positive Health Programme implementation was estimated to cost an average of £408 per participant. The intention-to-treat analysis showed that the PHP intervention costs £22,198 per QALY gain. The probability that PHP would be cost-effective is 44% (65%) if the policy-makers are willing to pay £20,000 (£30,000) per QALY gain. Nevertheless, PHP was highly cost-effective for those who attended at least 5 PHP sessions. For those who participated in 5–8 sessions, the PHP cost £9,040 per QALY gain. At £15,000 willingness to pay, the mean net monetary benefits from PHP were £255 for those attending 5–8 PHP sessions.

Equality, diversity and inclusion

This project has centred on the NIHR vision to 'provide better health and care through more inclusive research'. All efforts were made to develop a recruitment and retention strategy through the project to ensure engagement of this under-represented group. The research team were predominantly from ethnic minority backgrounds and through their

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time on the project the CI and trial management group worked to develop skills in research capacity and capability. Text and pictures, used as part of participant and public engagement, were inclusive and accessible to this research group. All study materials were translated and available in key South Asian languages (Urdu, Punjabi, Gujarati, Hindi, Bengali and Tamil).

Chapter 11 Add on study report – impact of COVID-19

Summary

The additional work stream is an add-on study to the ROSHNI-2 project (14/68/08, HTA) (IRAS 187851). The work was shaped by suggestions made by participants in the main ROSHNI-2 study for a follow-up and re-engagement to explore associated risk factors related to maternal mental health and specifically in the context of the pandemic. The NIHR HTA programme funded the study following a call for additional work building on existing grants.

We aimed to increase the understanding of the pandemic-related impact on BSA women, including IPV. The add-on study research design and survey tool were informed by an MRC-funded international survey study.[143]

Background

Pre-pandemic health disparities have been exacerbated by the impact of COVID-19, which has raised concerns that disparities in maternal health outcomes have also worsened. A recent study indicates that BSA women are four times more likely than white women to be admitted to a hospital with COVID-19-related complications during pregnancy (MBRRACE-UK, 2022). Public Health England (PHE) reiterates the importance of funding culturally competent health promotion and disease prevention programmes. Recently, an 'improving equity and equality in maternity and neonatal care' strategy led by NHS England (Maternity Transformation Programme, September 2021) was launched.

In addition, IPV remains a major public health concern in the UK. Despite growing recognition of the problem, it is an under-researched area. The current crisis of IPV has been heightened further with the COVID-19 pandemic. IPV is a highly prevalent phenomenon in BSA communities but under-reported. BSA women who face IPV are not only at a higher risk of depression and post-traumatic stress disorder but may also remain entrapped in violent relationships to maintain the family 'honour'.

Aim and objectives

This study aims to increase the understanding of the pandemic-related impact on BSA women and IPV in BSA communities. The objectives are as follows:

- To explore and understand the wider consequences of the global pandemic on BSA women during the postnatal period in the context of mental health, isolation, education, child development and views on the vaccination and wider impacts.
- To examine BSA women's experience of IPV to understand: risks, protective factors, barriers to help-seeking, challenges and IPV interventions for BSA survivors.

Methods

Design

We used a mixed-method study using an online survey adapted from *Psychological impact of COVID-19 pandemic and experience: an international survey* (IRAS PROJECT ID: 282858; Rathod *et al.* 2021, 2020) and one-to-one interviews (January–August 2022). The sampling approach used for online surveys and one-to-one interviews was purposive sampling of the participants screened on the ROSHNI-2 trial in the five study centres (North West, Yorkshire, East Midlands and London).

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Online survey
An online survey platform [Qualtrics® (Qualtrics, Provo, UT, USA)] was created to collect data from participants. The survey was launched on 3 January 2022 and remained open until 31 August 2022.

Consent
The ROSHNI-2 sample group had previously consented to the ROSHNI-2 trial and provided consent to be contacted for future research opportunities. The aim of the survey was explained in an introductory statement on privacy and confidentiality, and voluntary participation was made clear by reminding participants that they could leave the survey at any stage by closing it and that their answers would be kept anonymous. Full consent was obtained from all participants for the online survey.

Recruitment
The ROSHNI-2 sample of women were invited via an invitation e-mail and text messages with a link to the online survey. Research assistants contacted participants with no digital access via telephone. In addition, the survey link was promoted using various social media sites, including Instagram, Twitter, Facebook and WhatsApp channels.

Research assistants from each of the five study sites accessed secure databases to retrieve ROSHNI-2 participant information. The method of contact depended on factors including – time of day (using text messages during busy periods, including school pick-up times, evenings and weekends) and language (using phone-call to communicate with women who did not speak or read English). The IPV screening tool (HITS) was integrated into the survey. Those who scored high were then prompted to complete additional IPV assessments and were asked to provide contact details (optional) for a one-to-one interview.

All participants were provided with a Qualtrics link to the COVID-19 substudy to complete their questionnaire in their own time. Participants that requested support with the questionnaire were guided via a phone call, and questions were translated and marked accordingly on the online system. The survey was accessible in all study languages. All participants were offered an opportunity to enter a prize draw on completing the questionnaire.

Procedure
To ensure the responses were only from those who had previously taken part in the ROSHNI-2 project, participants were asked to indicate their level of engagement and contact with ROSHNI-2 (e.g. 'Have you previously completed a questionnaire for the ROSHNI-2 Project?'). This allowed any responses from those outside the target sample to be omitted from the final analysis.

Measures
Participant attitudes to the COVID-19 pandemic/restrictions were first measured, followed by levels of IPV, drug use, access to mental health support, impact on communication, loneliness and impact on child-care support. As well as measuring participant responses to these topics, the PHQ-9 and GAD-7 were also completed as part of the survey.

One-to-one in-depth interviews
The study team developed a topic guide for ROSHNI-2 participants and stakeholders (health professional and service providers) with input from PPIE groups.

Consent
Participants provided consent for the one-to-one interview using an electronic link prior to the interview. Participants with no digital access provided consent verbally on an audio recorder. All telephone interviews were audio recorded and transcribed verbatim with participant consent.

Potential stakeholders were identified using the research teams existing contacts and snowball sampling. Stakeholders were sent an e-mail with the details of the study inviting them to participate in the study, a copy of the PIS, and a link to a digital consent form (developed using Qualtrics). Participants were eligible to participate if they had had experience working with BSA women during the perinatal period and women exposed to IPV. All participants provided full consent

using the electronic link. All participants completed interviews online using Zoom (Zoom Video Communications, San Jose, CA, USA) or MS Teams. The interviews lasted roughly 1 hour.

Data analysis

Interviews were video recorded on MS Team or Zoom platforms with the auto-transcriptions feature enabled. Research assistants checked, edited, and confirmed verbatim auto-transcriptions recordings. Telephone interviews were transcribed verbatim into written text. Interviews conducted in languages other than English were translated and transcribed. All interview transcripts were imported into the Nvivo software application to manage and organize the coding of the data; transcripts were coded jointly by two researchers and reviewed as a group to achieve reliability.

The data were analysed using framework analysis, using the five stages to analyse the qualitative data: familiarisation; constructing an initial thematic framework; indexing and sorting; reviewing data extracts; and data summary and display, monitored by process of abstraction and interpretation.[144] The preliminary groupings were developed based on particular transcripts selected to categorise the themes. After that, the descriptive framework was reviewed to identify any connection and likeness between categories. The final stage of the analysis involved examining the level of matching between the occurrences distributed across the whole data set. The framework analysis identified key themes to explain the BSA women's experience of pandemic-related impact and IPV.

Patient and public involvement

We consulted with four PPI groups across Bolton, Manchester, London and Lancashire. The groups consisted of 25 BSA mothers with lived experience (previous ROSHNI-2 participants) in Bolton, Manchester, London and Lancashire. The PPI activities aimed to gain insight into the participants' opinions to develop a topic guide for the one-to-one interviews with ROSHNI-2 participants, health professionals and service providers on how we conduct the study and the viability of online survey and the one-to-one interviews. We conducted hybrid (face to face and virtual) group discussions (two hours) to inform us of the study design, research topic and outcomes. Two bilingual facilitators were allocated to each PPI group according to language preferences.

The group feedback helped shape, refine and confirm the research topic guide for the one-to-one interview and the contents and format of the online survey. PPI activity outcome included changes in the interview topic guide for women with lived experience and professionals' perspectives. Participants prioritised needs and discussed feedback drafts. The need for clear, valuing, non-stigmatising language in the interview was identified, particularly highlighting the sensitive nature of how the COVID-19 pandemic affected BSA women differently. PPI contributors had an overall positive attitude towards the study design and using online platforms for the data collection.

Results

Online survey

Researchers contacted potential participants for this add on work from the original cohort of ROSHNI-2 participants. Participants were contacted via text message with a link to the survey study and also with follow-up calls. A total of 1485 participants were sent text messages with details of the study by a ROSHNI-2 researcher and 387 of these were followed up with a phone call as per their request. In total, 267 responses were received, 27 of which were later omitted from the study due to not meeting the criteria of being from the original ROSHNI-2 sample of participants. Thus, a total of 240 responses was used for the final analysis. The baseline demographic characteristics of study participants are presented in *Table 34*. More than half of the study participants were between 25 and 34 years. Pakistani (*n* = 106, 44%) and Indian (*n* = 104, 43%) were the two most common ethnicities who completed this survey. The majority of the participants (*n* = 223, 93%) identified themselves as Muslim followed by Hindus (5%) and Sikhs (1.7%). About 96% (*n* = 231) of the survey participants were married and about half of the study participants (*n* = 122, 51%) had attended university. Of all who completed this survey, 177 (74%) were from North West of England and 47 (19%) from London. Regarding living status of survey participants, 126 (53%) owned their home, 75 (31%) had rented accommodations and 30 (13%) lived with an extended family (*Table 34*).

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TABLE 34 Demographic characteristics of survey participants

Baseline characteristics		Frequency	Percentage (%)
Age group	21–24	2	0.8
	25–34	140	58.3
	35–44	90	37.5
	45–55	8	3.3
Ethnic group	Indian	104	43.3
	Pakistani	106	44.2
	Bangladeshi	20	8.3
	Sri Lankan	4	1.7
	Any other South Asian background	4	1.7
	Prefer not to say	2	0.8
Religion	Islam	223	92.9
	Sikhism	4	1.7
	Hinduism	12	5.0
	No religion	1	0.4
Marital status	Married	231	96.3
	Separated	4	1.7
	Divorced	3	1.3
	Civil partnership	1	0.4
	Prefer not to say	1	0.4
Level of education	Left school before the age of 16	29	12.1
	Left school aged 16	17	7.1
	Left education aged 18	52	21.7
	Attended university	122	50.8
	Other (please specify)	13	5.4
	Prefer not to say	7	2.9
Location	North East	6	2.5
	North West	177	73.8
	Midlands	5	2.1
	London	46	19.2
	South East	1	0.4
	Prefer not to say	5	2.1
Living status	Own home	126	52.5
	Extended family (parents or in-laws)	30	12.5
	Rented accommodation	75	31.3
	Shared housing	1	0.4
	Other	6	2.5
	Prefer not to say	2	0.8

Participant's health during COVID-19

Survey participants were asked about COVID-19-related restrictions in their area and 197 (82%) said there were no more any restrictions, 10 (4%) said there were still restrictions, and 33 (14%) were unsure about it. Since the start of the COVID-19 pandemic till the time of survey, 90 (38%) of the participants and 125 (52%) of the family members of the study participants had been diagnosed with COVID-19. Also, 18 (8%) of the participants had experienced 'long COVID' and 43 (18%) had been diagnosed with one of the variants. Regarding COVID-19 vaccination, 33 (14%) participants had received first dose and 172 (72%) had received both doses of the vaccine. Regarding the booster dose, 80 (33%) women in the sample had received the booster vaccination, while 25 (10%) opted not to take the available COVID-19 vaccine. Of all those who had received the vaccination, 71 (30%) felt more relaxed, while 65 (27%) felt worried or anxious after receiving the COVID-19 vaccine.

Participants were asked about their attitude towards receiving the vaccine and 71 (30%) had a positive attitude towards it, 42 (18%) felt quite uneasy, 36 (15%) were neutral, 20 (8%) were very keen, 19 (8%) were not sure, 10 (4%) preferred not to say, and 8 (3%) were against it. Regarding participants willingness to get the vaccine, 102 (43%) were willing to get it, 43 (18%) were eager to get it, 24 (10%) were not bothered to get it, 24 (14%) were not willing to get it, and 6 (3%) were against the vaccination. When questioned regarding opinion of their family or friends about getting the vaccine, 64 (27%) stated they would encourage them, 63 (26%) strongly wanted to encourage them, 43 (18%) would not say anything to them, 12 (5%) felt their family/friends would suggest them to not get the vaccination, and 3 (1%) would ask them to delay getting the vaccination. The importance of the COVID-19 vaccination was also assessed among survey participants. The responses were: considered important by 71 (30%), really important by 67 (28%), neither important nor unimportant by 35 (15%), unimportant by 9 (4%), really unimportant by 3 (1%) participants, whereas 'Don't know' and 'Prefer not to say' was reported by 26 (11%) and 11 (5%) participants, respectively. Survey participants were asked about taking the COVID-19 vaccine during pregnancy and 84 (35%) said 'Definitely not', 31 (13%) said 'Probably not', 26 (11%) said 'Probably yes', 20 (8%) said 'Definitely', 13 (5%) said 'May or may not', while 25 (10%) said 'Don't know'. Participants were also asked if they took the vaccine during the first year after giving birth or during breastfeeding and the responses were 'Definitely yes', 'Probably yes', 'May or may not', 'Probably not', 'Definitely not' and 'Don't know' by 38 (16%), 38 (16%), 18 (8%), 27 (11%), 62 (26%) and 17 (7%) participants, respectively.

Domestic violence

Participants were asked if they had experienced (witnessed or suffered from) domestic violence in their home during COVID-19: 220 (92%) said 'No', 12 (5%) said 'Yes but not currently', 2 (1%) said 'Yes within past month' and 6 (3%) preferred not to say. *Table 35* illustrates the types and frequency of domestic violence experienced by survey participants.

Psychological impact of COVID-19 on survey participants

Among all, two (0.8%) participants had used medication other than that required for medical reasons, and one (0.4%) participant used more than one medication at a time. Of the total survey participants, 26 had a diagnosed mental health

TABLE 35 Types and frequency of domestic violence experienced by survey participants

Domestic violence	Never, *n* (%)	Rarely, *n* (%)	Sometimes, *n* (%)	Fairly often, *n* (%)	Frequently, *n* (%)	Prefer not to say, *n* (%)
How often does your partner physically hurt you?	7 (2.9)	4 (1.7)	2 (0.8)	0	0	1 (0.4)
How often does your partner insult or talk down to you?	2 (0.8)	1 (0.4)	2 (1)	6 (2.5)	2 (0.8)	1 (0.4)
How often does your partner threaten you with physical harm?	5 (2.1)	2 (0.8)	4 (1.7)	3 (1.3)	0	0
How often does your partner scream or curse at you?	1 (0.4)	2 (0.8)	3 (1.3)	6 (2.5)	1 (0.4)	1 (0.4)

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condition and these included 18 (8%) participants having anxiety, 17 (7%) depression, 7 (3%) panic attacks, 5 (2%) post-traumatic stress disorder and 1 (0.4%) attention deficit disorder and PND each. Diagnosis of mental health disorder was before COVID-19 pandemic among 16 (6.7%) study participants and after pandemic among 8 (3.3%) participants.

Participants responded to who currently supported them with their mental health and 13 (5.4%) of the participants mentioned a counsellor/psychologist/psychotherapist, 12 (5%) GP, 1 (0.4%) family, therapist, and work, while 7 (3%) said they had no support currently. During the time of COVID-19 pandemic, when questioned about what impact the support had on their mental health, nine (4%) participants said it stayed the same, seven (3%) said it decreased, six (2.5%) said increased, while four (1.7%) were not sure. Regarding method of support and whether it changed from face to face to other types, 12 (5%) were affirmative, 4 (1.7%) said there was no change, 6 (2.5%) were not sure while 1 (0.4%) participant said that the support did change for a while but currently face-to-face support had resumed (*Table 36*).

Participants were also asked if ever in the past 3 months, they had wished they were dead or had wished to go to sleep and not wake up. To this, 18 (7.5%) participants said yes while 6 (2.5%) preferred not to say. Further, 10 (4.2%) of the participants confirmed that they had a thought of harming themselves during the last 3 months. When asked if these thoughts had worsened or increased since the time of restrictions, 6 (2.5%) were affirmative while 19 (7.9%) were not sure.

COVID-19-related worries

Various COVID-19-related scenarios had been presented to survey participants to assess how worried they felt, and participants responded they were extremely worried about transmitting the virus to a vulnerable person (*n* = 93, 38.8%), the virus impacting their long-term physical (*n* = 57, 23.8%) and mental health (*n* = 45, 18.8%). A quarter of the participants were worried how COVID-19 was impacting their finances (*n* = 60) and how it would impact the society (*n* = 59). There was an additional worry related to experiencing another wave of the pandemic (*n* = 63, 26.3%).

Patient Health Questionnaire-9

The mean PHQ-9 score of survey participants was 5.37 ± 5.65. Severe depression was found in 8 (3.3%), moderately severe depression in 9 (3.8%), moderate depression in 35 (14.6%), mild depression in 60 (25%) and 128 (53.3%) had no or minimal depression.

Generalised Anxiety Disorder-7

The participants' mean score for anxiety on GAD-7 was 3.4 ± 4.8. Of all the participants, 170 (70.8%) had minimal or no anxiety, 42 (17.5%) had mild, 17 (7.1%) had moderate, whereas 11 (4.6%) had severe anxiety.

Impact of Events Scale – revised

The mean score of participants on the Impact of Events Scale was 11.2 ± 17.9. About 191 (79.6%) of the participants had no post-traumatic stress disorder (PTSD) while 19 (7.9%) had partial PTSD, 7 (2.9%) had probable diagnosis of PTSD and 23 (9.6%) had PTSD.

TABLE 36 Participants response to type of consultation they received and preferred

Type of consultation	Type of consultation received, *n* (%)	Preferable type of consultation, *n* (%)
Telephone consultations	7 (2.9)	5 (2)
Video consultations	1 (0.4)	1 (0.4)
Face-to-face contact	1 (0.4)	3 (1.3)
A mixture of telephone and video consultations	1 (0.4)	0
A mixture of telephone and face-to-face consultations	1 (0.4)	2 (0.8)
A mixture of video and face-to-face consultations	1 (0.4)	0

Ways of coping

Participants were asked how often they communicated with friends or family and were presented different methods of communication as options. A majority used messaging services such as WhatsApp, text messages, Facebook messenger, etc., several times a day (*n* = 93, 38.8%) to stay connected. Phone calls (21.7%), video calls (14.2%), and face-to-face interactions (10.8%) were other ways to stay connected. The impact of COVID-19 on a participant's relationship with family and friends was also asked in the survey. A total of 81 (33.8%) participants said they felt closed to family and friends, 80 (33.3%) felt isolated, 73 (30.4%) said that they were talking more, 60 (25%) said they had not noticed any change, while 9 (3.8%) said they were having more arguments. Participants were also asked how confident they were in coping with pandemic-related stress and these responses are presented in *Tables 37–39*.

Loneliness was assessed among survey participants and the results indicated that 148 (61.7%) did not feel lonely, 85 (35.4%) felt lonely, while 7 (2.9%) preferred not to say. Participants were also asked their opinion about perceived social support and in this regard various statements were given to them. Their responses are presented in *Table 6*. In this regard various statements were offered. Their responses indicated that most of the participants had a special person around them when needed (*n* = 108, 45%), with whom they could share their joys and sorrows (*n* = 114, 48%). They also agreed that their family tried to help them (*n* = 177, 65.4%) and that they got the emotional support and help needed from the family (*n* = 152, 63.4%). The participants also had friends with whom they could share their problems and joys (*n* = 130, 54.2%) (*Tables 35* and *36*).

TABLE 37 Participants' response to how worried they feel about various scenarios in relation to COVID-19

Scenarios	Not at all, *n* (%)	A little bit, *n* (%)	Moderately, *n* (%)	Quite a bit, *n* (%)	Extremely, *n* (%)
Getting COVID-19 yourself	58 (24.2)	70 (29.2)	39 (16.3)	36 (15)	34 (14.2)
Transmitting COVID-19 to someone else	51 (21.3)	54 (22.5)	28 (11.7)	47 (19.6)	56 (23.3)
Transmitting COVID-19 to your friends/family	45 (18.8)	49 (20.4)	31 (12.9)	44 (18.3)	66 (27.5)
Transmitting COVID-19 to a vulnerable person	42 (17.5)	40 (16.7)	24 (10)	37 (15.4)	93 (38.8)
COVID-19 impacting on your long-term physical health	57 (23.8)	52 (21.7)	37 (15.4)	37 (15.4)	57 (23.8)
COVID-19 impacting on your mental heath	76 (31.7)	45 (18.8)	29 (12.1)	45 (18.8)	45 (18.8)
COVID-19 impacting on your employment	120 (50)	32 (13.3)	16 (6.7)	18 (97.5)	42 (17.5)
COVID-19 impacting on your ability to care for others, including animals	62 (25.8)	63 (26.3)	29 (12.1)	38 (15.8)	47 (19.6)
COVID-19 impacting on your finances	74 (30.8)	38 (15.8)	19 (7.9)	46 (19.2)	60 (25)
COVID-19 impacting on your friends/family	35 (14.6)	59 (24.6)	44 (18.3)	52 (21.7)	47 (19.6)
COVID-19 impacting on society as a whole	39 (16.3)	57 (23.8)	33 (13.8)	47 (19.6)	59 (24.6)
Experiencing another wave of the pandemic	48 (20)	52 (21.7)	28 (11.7)	45 (18.8)	63 (26.3)
Things opening up too soon	99 (41.3)	46 (19.2)	36 (14.6)	37 (15.4)	16 (6.7)
Others not wearing masks	107 (44.6)	38 (15.8)	36 (15)	21 (8.8)	28 (11.7)
Going into your place of work	141 (58.8)	26 (10.8)	21 (8.8)	18 (7.5)	16 (6.7)
Mixing with those who have not been vaccinated	125 (52.1)	34 (14.2)	29 (12.1)	23 (9.6)	19 (7.9)

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TABLE 38 Participants' ways of coping during the COVID-19 pandemic

(a) Participants' method of communication with family and friends				
Communication method	**Several times a day, *n* (%)**	**Daily, *n* (%)**	**Every few days, *n* (%)**	**Not at all, *n* (%)**
Messaging services (such as WhatsApp, text messages, Facebook messenger, etc.)	93 (38.8)	88 (36.7)	51 (21.3)	6 (2.5)
Telephone calls	52 (21.7)	99 (41.3)	78 (32.5)	9 (3.8)
Video calls	34 (14.2)	73 (30.4)	94 (39.2)	36 (15)
Social media	50 (20.8)	63 (26.3)	57 (23.8)	66 (27.5)
Face to face	26 (10.8)	55 (22.9)	99 (41.3)	56 (23.3)

(b) Participants' response on how confident they were when faced pandemic-related stress					
	Not at all, *n* (%)	**A little bit, *n* (%)**	**Moderately, *n* (%)**	**Quite a bit, *n* (%)**	**Extremely, *n* (%)**
Support yourself to cope well in the situation	22 (9.2)	44 (18.3)	52 (21.7)	46 (19.2)	69 (28.8)
Support those around you to cope well in the situation	17 (7.1)	43 (17.9)	56 (23.3)	54 (22.5)	66 (27.5)

(c) Loneliness among survey participants			
Items for loneliness scale	**Hardly ever, *n* (%)**	**Some of the time, *n* (%)**	**Often, *n* (%)**
How often do you feel that you lack companionship?	129 (53.8)	67 (27.9)	35 (14.6)
How often do you feel left out?	132 (55)	63 (26.3)	34 (14.2)
How often do you feel isolated from others?	131 (54.6)	67 (27.9)	35 (14.6)

TABLE 39 Participant response regarding COVID-19-related perceived social support

	Very strongly disagree, *n* (%)	**Strongly disagree, *n* (%)**	**Mildly disagree, *n* (%)**	**Neutral, *n* (%)**	**Mildly agree, *n* (%)**	**Strongly agree, *n* (%)**	**Very strongly agree, *n* (%)**
There is a special person who is around when I am in need	15 (6.3)	11 (4.6)	9 (3.8)	24 (10)	23 (9.6)	41 (17.1)	108 (45)
There is a special person with whom I can share my joys and sorrows	16 (6.7)	9 (3.8)	11 (4.6)	17 (7.1)	28 (11.7)	38 (15.8)	114 (47.5)
My family really tries to help me	11 (4.6)	12 (5)	10 (4.2)	24 (10)	20 (8.3)	55 (22.9)	102 (42.5)
I get the emotional help and support I need from my family	14 (5.8)	8 (3.3)	14 (5.8)	22 (9.2)	25 (10.4)	47 (19.6)	105 (43.8)
I have a special person who is a real source of comfort to me	13 (5.4)	10 (4.2)	11 (4.6)	18 (7.5)	28 (11.7)	45 (18.8)	109 (45.4)
My friends really try to help me	14 (5.8)	16 (6.7)	15 (6.3)	38 (15.8)	24 (10)	55 (22.9)	66 (27.5)
I can count on my friends when things go wrong	17 (7.1)	19 (7.9)	18 (7.5)	34 (14.2)	33 (13.8)	46 (19.2)	64 (26.7)
I can talk about my problems with my family	10 (4.2)	20 (8.3)	11 (4.6)	28 (1.7)	323 (13.3)	47 (19.6)	87 (36.3)

TABLE 39 Participant response regarding COVID-19-related perceived social support (*continued*)

	Very strongly disagree, *n* (%)	Strongly disagree, *n* (%)	Mildly disagree, *n* (%)	Neutral, *n* (%)	Mildly agree, *n* (%)	Strongly agree, *n* (%)	Very strongly agree, *n* (%)
I have friends with whom I can share my joys and sorrows	15 (6.3)	15 (6.3)	14 (5.8)	27 (11.3)	33 (13.8)	59 (24.6)	71 (29.6)
There is a special person in my life who cares about my feelings	18 (7.5)	8 (3.3)	4 (1.7)	19 (7.9)	38 (15.8)	41 (17.1)	103 (42.9)
My family is willing to help me make decisions	13 (5.4)	10 (4.2)	8 (3.3)	33 (13.8)	28 (11.7)	42 (17.5)	101 (42.1)
I can talk about my problems with my friends	16 (6.7)	8 (3.3)	20 (8.3)	28 (11.7)	36 (15)	41 (17.1)	85 (35.4)

Child care, homeschooling, infant feeding and development

Survey participants were asked about child-care arrangements prior to pandemic, for which 48 (20%) participants mentioned home-based care, 39 (16.3%) said grandparents or other relatives, 26 (10.8%) said other options, 3 (1.3%) said in home nanny, whereas 89 (37.1%) said that they had no child care. With regard to the number of hours per week for child-care arrangements utilised by participants and how they were affected during the pandemic restrictions, 49 (20.4%) of the participants said that these child-care restrictions impacted productivity at work level, while 29 (12.1%) said that there was no impact. Further, 53 (22.1%) participants said that these restrictions on child care had impacted their stress and anxiety levels, while for 26 (10.8%) there had been no impact.

For managing household chores with child care restrictions, 56 (23.3%) said it had been impacted and 22 (9.2%) said it had not. Regarding children's home-schooling arrangements during the lockdown, 34 (14.2%) participants said they had used content created and shared only by the school, 59 (24.6%) said they had used both school- and parent-created content, while 104 (43.3%) said other (i.e. out of school or homeschooled prior to the pandemic).

The closure of children's centres and support groups affected 99 (41.3%) of the participants, while 130 (54.2%) said they had not been affected. In addition, 119 (49.6%) of the participants experienced concerns about their child's development during the pandemic. When the participants were further asked about the specific area of child development in which they had concerns, 89 (37.1%) said in social, 62 (25.8%) in language, 57 (23.8%) in emotional, 53 (22.1%) in cognitive/learning outcomes and 45 (18.8%) in physical area of development.

Of all participants, 133 (55.4%) breastfed their child, 97 (40.4%) had not, and 10 (4.2%) preferred not to say. Of those who breastfed, 32 (13.3%) did it for < 6 months and 98 (40.8%) did for more than 6 months. There were 76 (31.7%) participants who had breastfed their baby during the pandemic. When questioned about how the pandemic had impacted their breastfeeding practices, 20 (8.3%) participants mentioned the impact on frequency, 9 (7.9%) duration of breastfeeding, and 18 (7.5%) said that their plan of breastfeeding was impacted due to the pandemic. Participants were also asked about the possibility of testing positive with COVID-19 and if it would impact their concern about breastfeeding their child and chances of transmission. Of the participants, 145 (60.4%) said no, while 22 (9.2%) said yes. However, 63 (26.3%) felt they would have benefitted from additional support/advice with breastfeeding from the mid-wife team/health visitors.

One-to-one interviews – health professional and service providers' perspectives

A total of 10 interviews were conducted with health professionals and service providers (*Table 40*); all participants were female; eight participants were of BSA background, and two were of White British background; eight were based in the North West and one in South Yorkshire and one in London.

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TABLE 40 Stakeholder interviews

Health discipline/service	
Midwife	3
General practitioner	1
Domestic abuse service	3
Third sector organisation	2
Children's services	1

Increase in interpersonal violence referrals and reporting

Although the lockdowns were implemented for protecting public health, these also created unintended impacts. The majority of participants perceived the lockdown as heightening the risk factors for IPV due to various reasons: increased financial strains due to loss of income as a result of unemployment and the lack of space or opportunities to avoid situations for those in unsafe relationships:

> *So one of the women I was talking to lived with her husband and his family, and during that first period of lockdown she was saying that she because her child was then not in school and not obviously not in childcare and that she, that the abuse from the husband's family really escalated and she would just keep herself and her child upstairs in in her bedroom, and like every time that she went downstairs, whether it was to get food or do washing or anything she knew that she was kind of open to abuse from husband's family.*
>
> *Third-sector organisation (NW-007)*

Social distancing and isolation meant IPV victims were at a higher risk and greater vulnerability, as many were forced to isolate with violent partners or family members. Many who were dependent on others for their immigration status were threatened and are often at risk of IPV. Participants talked about how for many BSA women, the limited private space isolated victims of IPV from their social support system as victims/survivors, limiting access to family and friends, the people they rely on, so increasing the risk of further violence.

> *… and across all of the clients that we've got, you know it's being stuck at home with the perpetrator 24/7 which is all of them have reported was the worst. And we know, I mean we've not got the statistics but you know reports to the police increased. Which, and you know the knock-on effect of living with the perpetrator and things so that has been.*
>
> *Domestic abuse service (NW-002)*

Although it was perceived that the increase in IPV reporting was due to the increased risk factors with lockdowns and pandemic restrictions, interestingly, a few participants highlighted that the lockdown provided the opportunity for many IPV victims the opportunity to report the abuse and seek help, which otherwise may not have been reported:

> *… And so she talked about having a consultation with the GP. The GP over the telephone. GP asked her is everything all right at home and she said no, she disclosed domestic violence, which she hadn't done before. Because every time she'd been to the GP surgery before her husband had been with her and she'd never been able to make a disclosure so that again it was a situation where the abuse she was experiencing had escalated because all this, all these people in his house were brought together. But the flip side of that was because of the difference in her GP appointment. She was able to make a disclosure, and she left the, so she did access support and she left an abusive relationship. So there was loads of kind of unexpected stories, I guess, from the women I spoke to.*
>
> *Third-sector organisation (NW-007)*

> *The ones that have, like I said, we gave the option if it's not safe for them to speak at home, come to the doctors surgery and we would get the receptionist to ring and say we need to check your bloods or something and call them in that way so we were quite fortunate because we've got those connections and those links.*
>
> *Domestic abuse service (NW-002)*

Participants also highlighted that BSA women with no recourse to public funds were at an exceptionally high risk due to their inability to access benefits and many statutory services. This also presented a barrier to disclosing personal circumstances, for example, mental well-being and IPV.

> *Even before the outbreak of COVID-19, women's access to specialist refuge provision in the UK was severely limited. These victims and survivors spend much longer in insecure, temporary accommodation than other groups.*
>
> *Third-sector organisation (LO-009)*

It was also highlighted that not all IPV victims can reach out for help, this was raised as a concern, particularly in the case of South Asian women, where the women are repeatedly deemed accountable for safeguarding the family 'honour', which has generated a history of under-reporting over the years and are forced to remain in abusive environments.

Increased home and care responsibilities

Many women were expected to take on domestic responsibilities such as cooking, cleaning and other obligations. Due to the lockdown, these women were additionally burdened with the expectation of educating their children and also looking after their in-laws and husband:

> *I think, staying inside, isolation, staying in the home, I think that made them think, that made them realize more on loads of things probably were just, you know, some time, usually in a, in a typical Asian family sort of set up, where woman look after children, cook food and stay home and husband goes out for work. But then, then people started working from home, then I think that it kind of sort of a reflection time to give, give them a more understanding that where the relationship is actually.*
>
> *Third-sector organisation (SY-003)*

Participants reflected that the overwhelming strain of additional household roles may have led to potential mental health difficulties for many South Asian women. Participants highlighted that previous to the lockdown, many young BSA women were able to use their independent lives (through work, friends, relationships, etc.) as a form of escape from the controlling environments often found at home; due to the lockdown, many found themselves entrapped without a release from the difficult home environment.

Mental health support

Participants who came in contact with service users highlighted their observation that service users faced many challenges due to the pandemic, ranging from loss in income and problems accessing healthcare services and other statutory services to difficult relationships at home and child-care-related challenges had played a part leading to a deterioration in their mental wellbeing. A participant highlighted:

> *We have seen depression which is more than normal, anxiety was more than normal because people were housebound and not working so we were getting more calls … I did notice there were more forms which the midwives were doing and expressing concerns.*
>
> *General practitioner (NW-006)*

Access to healthcare services

The COVID-19 pandemic essentially changed how patients accessed primary care; participants talked about the overnight rearrangements of patient contact, moving to remote consultations from face-to-face appointments. For some, this method provided accessibility; however, it also presented difficulties highlighted by participants as language and cultural barriers, which were more difficult to manage via remote consultations. Participants also highlighted that most did not have regular access to digital devices or were IT literate and may have limited access:

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> *There were barriers like people were finding it difficult to access GPs. They wouldn't come to the surgery, even when sometimes we when we thought we had to see the patient face to face for examination … But yes in White population they try their best to engage with health services. So they would attend accident and emergency, they would contact the GP.*
>
> *General practitioner (NW-006)*

The GP participant (NW-006) further highlighted the challenges in access of mental health services for patients:

> *Mental health is the I think the worst service I've got lots of friends who are psychiatrist, and I keep saying this. That been mental health was the most difficult, it still is even pre-COVID and after COVID just now also. If you refer to mental health, it takes ages, and most of the time the referrals are declined. That we are not suitable for this service referred to local like self-help, group mindful and mindfulness, and all those type of things with the sign posters to those services, plus even with the during the COVID time all of us have experience that even contacting mental health team for crisis was a nightmare. You have to ring 3, 4 numbers before you can find the right person.*

A participant highlighted the need for clear, accessible, locally relevant public information for BSA women, ensuring engagement in the continuity of maternity care provision measures, reassuring BSA women with regard to maternity care and seeking help with any concerns about their health and maternity care.

Interpreting services

Participants also highlighted the need for adequate regulation and standards agreed to ensure the use of appropriately trained interpreters.

> *Sometimes you know professionals still don't recognize that speaking to the woman alone, getting an independent interpreter is so important to do. Not trusting the smiling mother-in-law who looks like a lovely nice cute little old lady with her head scarf on. Its such a stereotype isn't it, that they believe that no she's a loving caring grandma and we thought it was okay to speak to her and we've closed the case because she said everything was fine. So I think a lot of work still needs to be done about awareness about honour based violence, about multiple perpetrators as well.*
>
> *Domestic abuse service (NW-002)*

Need for cultural competency and training

Cultural understanding and competence were highlighted as key factors ensuring the individual is respected, and the individual's culture is acknowledged and valued. On this note, another important point highlighted was recognising the different cultural practices or views within the South Asian community and recognising the intersectionality. Understanding the beliefs and their learnt notions of health and how their religious beliefs, traditional values and upbringing may play a role in their interactions with and access to health care or services.

A participant highlighted that cultural competence education for healthcare professionals would influence improved health outcomes for interacting and working with diverse patient groups to increase their empathy and by being able to understand and communicate effectively and help reduce health disparities:

> *I also think that that practitioners need cultural awareness. And that's really hard, because there isn't just one culture for any group of people. So you know, I think there's a danger in saying that British South Asian women all have the same culture, and therefore the same needs, or risks, or whatever. And yes, there's a danger of kind of homogenizing and logging people together, so understanding that level of difference in diversities is really hard. But on the flip side I think there is something about cultural competence, and people need to understand that there are differences. Similarly, if you're an older woman to a younger woman, there are additional aspects of your circumstances. And bits of your identity that that will come into play. If you, you know, if you are domestic violence victim.*
>
> *Third-sector organisation (NW-007)*

Challenging implicit bias and prejudice

A few participants stressed the importance of recognising the role of implicit biases of health care professionals creating disparities in healthcare as implicit bias and prejudice may undermine the goal of delivering impartial care: highlighting that a patient should not receive a lower standard of care due to her ethnicity or cultural background:

> *There are issues with care provided to South Asian women, there's a lot of issues. And I've had bias and prejudice and presumptive conversations around South Asian communities by healthcare professionals. It's sadly, one of those things that I historically didn't challenge because I didn't feel like I was able to. And now I have a way of challenging it in a respectful professional manner, and now people don't talk a lot about that around me anymore, so I'm not going to think that oh we've cured it, I just know that they know I will not let them have such conversation in my presence and. And that should tell them that it's a wrong conversation to have and the fact that they're saying that is incorrect because if they have to edit themselves, just because I'm in the room, then they should have the realization that it's wrong to say in the first place.*
>
> *Midwife (NW-001)*

The danger of BSA women being considered homogeneous and overlooking their intersectionality of socioeconomic status, ethnicity, religion, gender and immigration status was highlighted by participants. Furthermore, the need for conversation and to do it consistently was stressed by a participant, highlighting the depth and breadth of South Asians as a community with different subsets and cultural notions, which cannot be addressed by mainstream services in its totality to address all the different intricacies. Still, proactive engagement encourages open, consistent conversations can help to address such challenges.

Intervention

Participants made suggestions for IPV interventions, tailoring interventions to meet the needs of individuals, and ensuring culture-specific and trauma-informed strategies could be helpful for South Asian women. Culturally sensitive interventions comprising of meaningful understanding of the IPV contexts in which BSA women are placed, the community understanding, and experiences of mental health would help with engagement in interventions by BSA women:

> *I think one of the things that I worry about when we talk about standardizing or having a universal way of doing something, is that each family and each individual as much as we have things that link us they're all different and experiences are different so as much as we can standardize and we can have those practices. We also need to be conscious about having a personalized aspect of it, and understanding individual needs for people that might be in that group of that session.*
>
> *Midwife (NW-001)*

Although the value of involvement of the family in the intervention was recognised by participants, in the context of South Asian women, many participants felt that it would not work as, from their experiences, many perpetrators included intimate partners and BSA women's in-laws, extended family members and own family members.

One-to-one interviews – ROSHNI-2 participant's perspectives

The interviews with trial participants for the add-on study focused on gaining a better understanding of the effect of global pandemic on BSA women in the postnatal period and also aimed at getting the participants' perspectives on how future trials should be informed to address IPV. The findings are reported under the themes of mental health during the pandemic, perceived isolation, education, interpersonal relationships, child development, perspective on COVID-19 vaccination and future interventions.

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Mental health during the pandemic

Due to the pandemic and the lockdown, the participants reported higher anxiety and pressure. The anxiety was considerable because of the unknown nature of the virus and limited information available related to it. There was the added fear that perhaps the virus would never go away and that things will never get back to normal:

> *We did not know what was happening … perhaps this would remain like this forever … things would never improve … something bad is going to happen.*
>
> *Trial participant (NW-0192)*

Along with limited information available, the experience of having to stay within the confines of the home and not going out at all made the participants feel upset even more:

> *Getting to stay at home … it felt like it was a prison … with the complete lockdown, the children also became very upset and then not being able to do shopping … there were too many problems that came during that time and my depression really increased.*
>
> *Trial participant (NW-0192)*

The women explained that they struggled to get support from the GPs due to the closure of the surgeries and this was particularly difficult for those women who gave birth during this time. One of the participants reflected:

> *The COVID-19 obviously started in 2020 officially … I gave birth to my child in 2019 December. So for me, it was the hardest year to be honest. Because everything got changed the way you actually get help, the way you actually get your midwives, or anything like that, especially with the childbirth or postnatal care, everything has been changed and you got all your kids at home. So, to be honest, since 2020 it has been really really roller coaster ride for me, or any mother like me with kids. There was no appointments, you can't see your doctor. you can't speak to anybody, everything has been closed.*
>
> *Trial participant (NW-0173)*

The statement above identifies how the participants were struggling as they found it difficult to get the right kind of support. This affected their mental health, and some found it difficult to cope:

> *I'm a freak, I get a lot of anxiety with everything, it gives me a lot of stress and also my kids that get a lot of allergies like seasonal, so it was really difficult for me to you know this distinguish between if it's the virus or if it's just normal in our daily everyday sniffles so it was really difficult in the beginning but I was so panicky.*
>
> *Trial participant (LO-01)*

Another participant reported:

> *I remember being very anxious, as my husband has leukopenia so he has low white cells, and his cousin was on a ventilator from the flu because he has the same condition. So I was quite worried and scared for my husband.*
>
> *Trial participant (NW-0193)*

Perceived isolation

The pandemic was associated with a number of challenges including social isolation. One participant explained:

> *We used to feel upset, as we were not allowed to meet anyone in person, nor we were allowed to go at anybody's house. Neither anybody could come to your house. In the past we were very social, so it was difficult for us to live in isolation.*
>
> *Trial participant (NW-142)*

However, some of the participants also reported not feeling too much of a difference related to socialising or going out. This was because of their lifestyle even before the pandemic where they did not step out much out of the house, and therefore did not find things very different during the pandemic:

> *It did not impact me that much … actually I do not go to anybody's home … I do not talk also with many people … I don't also have any close friend here as such … with whom I can talk or go to her place every day … there is nothing like that.*
>
> *Trial participant (NW-0094)*

Another participant similarly mentioned:

> *To tell you the truth we generally do not meet many people … I do not have that much of a social life … it is not that much at all.*
>
> *Trial participant (NW-00192)*

Child education

Similar to other areas of life, the pandemic greatly impacted schooling and education. Children were at home due to school closures and, even though they were connected to the schools through online classes, had different routines from what they were used to. Almost all of the women who were asked about the distant learning responded that they favoured face-to-face classrooms rather than home schooling during the pandemic. One of the women shared:

> *It is best that children should attend school physically in a routine. There they learn more in contrast to home schooling.*
>
> *Trial participant (NW-00142)*

Similarly, another participant responded:

> *No, I believe online schooling was not very successful, my children sometimes used to pay attention to their online session, however, they use to put the laptop at a side while the teacher was still teaching. My son who is at the age of 13–14 was not very much interested in the online session and did not focus on his education as he should be doing.*
>
> *Trial participant (NW-00175)*

One of the women responded about the online schooling mentioning that she found this entire time particularly stressful due to managing so many things simultaneously and balancing housework with the children's schooling. She said:

> *Oh don't ask … it was very very difficult … you know managing house work and then this was something totally new for me … I have three kids and I have to sit down with three of them at different times … and I can't explain how I spent that time … sometimes I was fed up … and sometimes we used to miss some homework as well.*
>
> *Trial participant (NW-001)*

Some participants also felt that it was a good opportunity for them to spend time with their children and help them in their learning process.

> *I have never spent that much time with my son in his learning but now I managed to help him with handwriting and his spelling, because I felt he is not getting that kind of help from the school now with the closures. State schools were unfortunately not able to help like independent schools.*
>
> *Trial participant (NW-002)*

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Interpersonal relationships

The add-on study interviews also focused on the relationship between the participants and their spouses and the extended family members during the pandemic. Many participants reported that they did not come across any issues with their own spouse and did not report any incident of interpersonal violence, though they did mention incidents in their circle of acquaintance and hearing about increase in interpersonal violence through media reports.

One of the participants explained:

> *No really, I do not have my own personal experience of it, however, I used to learn from the news that this happened that happened, and actually come across through news that the divorce rate has gone up.*
>
> *Trial participant (NW-00173)*

A participant who mentioned physical violence with her spouse during the lockdown reported:

> *I think it did get physical only once, and that situation was only, like he's not a violent person. It was like he had his own health issues or due to his brain condition, I think, which why the incident occurred. That's one incident that we had where things did get physical.*
>
> *Trial participant (LO-01)*

A participant reported feeling a strain in her relationship with her husband during the pandemic which was heightened due to the fact that he lost his job whereas she still had hers. This had an impact on their interpersonal relationship:

> *Because you don't have a job and that it is very difficult for any British South Asian man to accept no matter how little they may be earning or how educated … he was getting very agitated over small things …*
> *if my daughter would come out of the room without socks it suddenly was my fault, because I should have put the socks on and suddenly she is walking around and sneezing while I am in a meeting and he is observing me working. I know I can't snap back because if I do, I might end up losing my marriage during the pandemic but he is getting quite difficult to deal with every time.*
>
> *Trial participant (NW-002)*

The same participant went on to add:

> *It very nearly got physical … my husband was under immense pressure to send money home which he couldn't because he was furloughed … so all the long hours on phone calls with his family while I was working in my room … added to his frustration and he took it all out on me … he was constantly blowing up on small things.*
>
> *Trial participant (NW-002)*

Stress on children

During the lockdown, children were confined to their house with online classes/distance learning. The closure of the schools for a seemingly indefinite period and the pandemic caused frustration and anxiety among children.

As a participant shared:

> *No, they didn't like the closures. My oldest one wanted to go to the school and needed some support in some subjects. He used to get stressed and used to start to cry saying that I don't know how to do it and teacher did not explain me. I know the teacher didn't have much time as well. So, he was getting a bit stressed on that side, he said no I don't like online schooling I want to go to the school so that they can help me.*
>
> *Trial participant (NW-0013)*

Furthermore:

> *H]onestly now, it makes me sad when I see my kids like when they're out and about and it's my little one that she almost four not even four yet and if she touches, anything, even you know when they walk in the park and she touches a bar that is around the lake, and my son, and even now my daughters like that do not touch this it is a coronavirus you need to disinfect your hand. That is wrong like this age, they were supposed to be free, and not you know pressurized by a virus and they going to get sick or eventually people will die.*
>
> *Trial participant (NW-LO1)*

A participant mentioned her child getting more aggressive and anxious during the pandemic:

> *Many people were mentally effected, one of my sons also use to feel agitated, he use to shout a lot and fight with his sibling very often. This could be clearly noticed that they also got fed up with the social isolation and if in the future the world will face anything like this, I believe it will be very painful for them.*
>
> *Trial participant (NW-04)*

Getting additional help from online tutors was also considered by a participant, although she did mention that she was not too happy, but there was not any choice. She felt that getting the children in a structured routine would be helpful since the children were spending too much of time on social media and video games:

> *Honestly, I was not too happy with it … we were paying per hour to this girl who used to give some worksheets to my son … but it was better than nothing. My children were frustrated, they were scared, they kept asking me questions... x box became a normal part of the day … my biggest job was to get them off the xbox … my children are very difficult to deal with, they know my every move … constantly they were on i-phones like hours are going by.*
>
> *Trial participant (NW-002)*

Perspectives on COVID-19 vaccination

Many of the participants had concerns and reservations about the vaccination and were not pleased to have it. Especially when it was inquired about the booster, they declined to have one nor showed any interest in getting one in the future.

One of the participants expressed her doubts about the effectiveness of the vaccine. She shared:

> *No, I didn't want to have, and it was the same thing that you are actually playing with the body, so this is something that you are not doing it right. Your body immunity is very strong, and it fight itself. So, you are actually playing with the immunity rather than anything else. I'm not well in any way, and that's what's been happening with me as well since I got my second vaccination. I am not good, I have so many issues so many problems so many things that I never experienced before. So yeah, I wouldn't say that this is a good option.*
>
> *Trial participant (NW-0173)*

While feeling hesitant to take the vaccination, one of the participants felt she took it in order to comply with the travel guidelines and regulations:

> *Yes, many rumours circulated but I was compelled to have the vaccination as I was not able to travel without it and I have family outside the UK so it was more of a compulsion then a choice.*
>
> *Trial participant (NW-01)*

One participant felt that even though there were several rumours about the vaccination, she took it because she fell into the vulnerable category:

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> *There were a lot of stories that circulated about the vaccination. Some people said they are putting in the chip in the body to control the human being. But I had no choice as I am a diabetic patient and I got a call from the NHS that I am vulnerable and should get the vaccination.*
>
> *Trial participant (LO-04)*

Vaccine hesitancy was particularly noticed in pregnancy and breastfeeding women as a participant spoke:

> *I did not take the vaccine because I am pregnant at that time and now I am breastfeeding so I am not sure whether to take it or not … there is also not much information available about how it impacts the baby … so I don't want to cause any harm to the baby. Actually, my husband has also not got it. He keeps saying that he will get it but he has not done so far … he has gone 4–5 times but always good back … I think he is scared.*
>
> *Trial participant (NW-0094)*

Future interventions

The participants were asked about how future interventions be informed, particularly addressing interpersonal violence. They were reminded about the PHP on which the ROSHNI-2 intervention was based, on the principles of CBT, and two further interventions were presented: (1) trauma-focused CBT – *Basid ki kahani* and (2) the Learning through Play parenting intervention. These interventions have been reported to be effective in South Asia. The participants were then requested to share what they thought needed to be included in addition to the content discussed with them.

Most of the participants said that the future interventions should be universal so that more people can benefit from them:

> *I like the idea of involving fathers as well as mothers, and generally as I suppose it should be open to everyone and everyone can benefit from it. Even foster parents or carer should also have access to it. These sorts of programmes would be so beneficial.*
>
> *Trial participant (NW-04)*

Another participant agreed to extend the intervention besides just women in the perinatal period:

> *I guess it depends who you are trying to target because I think interpersonal violence is not just for women, though is it. I think it effects both genders and I guess if we are seeing a bigger problem for women then I guess it is good for women only but I think children should also be included but it depends on the ages of the children.*
>
> *Trial participant (NW-0175)*

> *I think it should be universal, everyone should benefit from it.*
>
> *Trial participant (NW-0018)*

The participants also felt that including delivery of some sessions by religious leaders within the modules might prove to be beneficial for the participants:

> *I think if a maulvi or father from the church delivers some of the sessions, then more participants might listen or might attend because out of respect they want to agree with them.*
>
> *Trial participant (NW-0094)*

A participant felt that getting to know about one's rights and assertiveness training is very important for women, particularly to stand up against interpersonal violence:

> *It is extremely important that British South Asian women know their rights … they should know what their value is … this is something that is not often talked about … we should be able to stand up for ourselves … these kind of things should be included in the therapy sessions*
>
> *Trial participant (NW-00192)*

Next steps for impact and dissemination

- The differences in demographics and costs suggest that further work and research are needed to establish how best to ensure equitable services within primary care.
- Further research is necessary to support a better understanding of cultural competence to help improve cultural knowledge among healthcare professionals and IPV service providers.
- Health providers can help to mitigate the risk of IPV against women and help reduce its impact by signposting to many locally available support services (hotlines, crisis centres, shelters, legal aid, and protection and counselling services) for IPV survivors and referring BSA women to these services by strengthening engagement with the community.

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All authors have contributed to the development and approved the final version of this monograph.

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Patient and public involvement and engagement

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Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

Data-sharing statement

Reasonable requests for patient-level data should be made to the corresponding author and will be considered by the ROSHNI-2 trial management group. The ROSHNI-2 management team and sponsor will consider the sharing of data on a case-by-case basis in line with the ethics approval and patient information sheets. Any presented data do not contain any direct identifiers.

Ethics statement

The study was approved by the NorthWest Health Research Authority (ethics approval number: IRAS 187851; 6th January 2017), with each trial site granting individual NHS Trust approvals prior to recruitment at each site.

Information governance statement

Lancashire & South Cumbria NHS Foundation Trust is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679.

Under the Data Protection legislation, Lancashire & South Cumbria NHS Foundation Trust is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here www.lancsteachinghospitals.nhs.uk/privacy-notice.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/KKDS6622.

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Primary conflicts of interest: Bhui has membership with HS&DR Funding Committee (Bevan) from November 2020 to present. Davies has membership with HTA Clinical Evaluation and Trials Committee (date unknown), Williams has membership with HTA Commissioning Sub-Board (EOI) April 2016 to March 2017, HTA Funding Teleconference Members April 2015 to December 2015, HTA Commissioning Committee August 2011 to September 2017. Emsley has membership with NIHR CTU Standing Advisory Committee January 2020 to January 2024 and membership with the HTA Clinical Evaluation and Trials Committee. Gire is a member of the NIHR PHR Funding Committee from 2022 to present. Morriss has participation on the NIHR EME, HTA and HSDR trial steering committees and Data monitoring ethics committees.

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Cost-effectiveness of a group psychological intervention for postnatal depression in British south Asian women: an economic evaluation from the ROSHNI-2 trial

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Summary

Background Minority ethnic groups often face ethnocultural barriers in accessing mental health treatments. The ROSHNI-2 trial compared culturally adapted cognitive behavioural therapy (Positive Health Programme [PHP]) with treatment as usual for postnatal depression in British south Asian women. We aimed to assess the cost-effectiveness of the PHP intervention.

Methods The ROSHNI-2 trial was a multicentre, two-arm, assessor-blinded, randomised controlled trial; we conducted an economic evaluation over a 12-month period to assess the cost-effectiveness of PHP plus treatment as usual versus treatment as usual alone from the perspective of the English National Health Service and personal social services. In the trial, British south Asian women aged 16 years or older with a child aged up to 12 months, and meeting DSM-5 criteria for depression, were recruited from northwest England, Yorkshire, the East Midlands, and London. The PHP intervention involved 12 group sessions delivered by two trained bilingual facilitators, held once per week for 2 months and once per fortnight thereafter, each lasting 60–90 min. Questionnaires on depression symptoms, quality of life, and resource use were completed at baseline, 4 months (end of intervention), and 12 months after random assignment. Quality-adjusted life-years (QALYs) were used for the cost-utility analysis, and recovery from depression at 4 months (the primary clinical outcome), assessed using the Hamilton Rating Scale for Depression, informed the cost-effectiveness analysis. After the onset of the COVID-19 pandemic, the intervention was adapted for online delivery for the remaining participants. A stratified analysis compared the cost-effectiveness of online versus in-person delivery. The trial involved researchers with lived experience, and all methods, including health economic measures, were developed in consultation with service users, community members, and faith leaders. This is a preplanned analysis of the ROSHNI-2 trial, registered with ISRCTN (ISRCTN10697380).

Findings From Feb 8, 2017, to March 29, 2020, 732 eligible women were enrolled: 368 participants were randomly assigned to the PHP arm and 364 to the treatment as usual arm. The base-case intention-to-treat analysis showed that PHP significantly increased costs (£712, 95% CI 311 to 1113) and QALYs (0·036, 95% CI 0·006 to 0·067), with an incremental cost-effectiveness ratio of £19 601 (7622 to 83 772). Based on the UK National Institute for Health and Care Excellence (NICE) maximum willingness-to-pay threshold of £30 000 per QALY, the likelihood of PHP being cost-effective was 77% from a health and social care perspective. Cost per remission from depression at the 4-month follow-up was £5509 (2916 to 17 860). In a stratified analysis of 34 participants attending online sessions during the pandemic, incremental QALY effects were 0·125 (0·048 to 0·203), resulting in costs of £202 (–3906 to 10 918) per additional QALY gained.

Interpretation The average cost of PHP for postpartum women was below the lower end of the NICE threshold of £20 000–30 000 per QALY, excluding benefits to the child or potential gains such as reduced lost productivity from early remission. PHP, a culturally adapted group cognitive behavioural therapy-based intervention, might be a cost-effective intervention for postnatal depression in British south Asian women. Online PHP delivery showed promising clinical and cost-effective results for this group but requires a large-scale study.

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Introduction

Postnatal depression is a major global health issue, affecting 17% of women in the postpartum period (ie, first year after childbirth), with significant negative effects on both mother and infant.[1] Approximately 30% of affected women continue to have depression beyond the postpartum period, with a 40% risk of relapse.[2] For the mother, postnatal depression increases the likelihood of chronic disease, substance misuse, breastfeeding difficulties, relationship problems, job loss, and suicide.[3,4] Postnatal depression can also affect children through impaired bonding and attachment (ie, mother-to-infant

Research in context

Evidence before this study

The Medline library was searched via the Ovid MEDLINE database using MeSH terms: "depression" OR "postpartum" AND "cost-effectiveness analysis" OR "cost-utility analysis" OR "economic evaluation" from database inception to Oct 21, 2024, with no language restrictions. Google searches using the same terms and time period were also done. We identified two systematic reviews on the cost-effectiveness of pharmacological and non-pharmacological depression treatments in high-income and low-income countries (covering 2000–22). The Thinking Healthy Programme, a low-intensity therapy-based intervention, and its group delivery adaptations, showed a high clinical effectiveness for prenatal depression when delivered by trained non-specialists in south Asia or to British south Asian women. Two trial-based studies assessed the cost-effectiveness of the Thinking Healthy Programme for maternal depression in Pakistan and India when delivered by peers. In Pakistan, the Thinking Healthy Programme intervention cost $236 (2015 US dollars) per individual recovery from depression at 6 months postpartum, and in India, it was cost-saving (dominating treatment as usual). Both studies were rated high quality. In high-income countries, only two studies assessed therapy-based interventions in disadvantaged populations. One study evaluated the effectiveness of enhanced home visit engagement using motivational interviewing and brief cognitive behavioural therapy or interpersonal therapy for 25 low-income, minority ethnic pregnant and postpartum women, but this did not include an economic evaluation. Another study found that in-home cognitive behavioural therapy for low-income women with major depressive disorder in a home visiting programme (n=93) was cost-saving in the USA, reducing expected depression days compared with usual care. None of the other identified studies included economic evaluations of interventions targeting specific minority ethnic or socioeconomic groups. To address this evidence gap, the National Institute for Health and Care Research Health Technology Assessment Programme commissioned the ROSHNI-2 trial to generate further evidence.

Added value of this study

This study evaluated the cost-effectiveness, alongside a large-scale randomised controlled trial, of a programme specifically designed for British south Asian women, who have a higher prevalence of postnatal depression, higher birth rates, live in low-income areas, and are less likely to seek professional help. To our knowledge, it is the first evaluation of culturally adapted group therapy, delivered by non-professional bilingual facilitators (in five languages) for women with ethnolinguistic barriers, with facilitators matched to participants' language preferences. The cost-effectiveness analysis suggests that the therapy improves the quality of life for British south Asian women at a justifiable cost (£19 601 per QALY). The higher QALYs observed among those attending full or partial online sessions indicate that future costs could be reduced by exploring online or blended delivery models.

Implications of all the available evidence

With each episode of perinatal depression in the UK estimated to have a lifetime cost of £75 000 for the mother and child, and considering the cultural and linguistic needs of minority ethnic groups, PHP might be a cost-effective intervention for postnatal depression in minority ethnic women. Mental health research and services risk excluding minority ethnic groups if they overlook cultural, social, and language barriers. Emerging evidence suggests that culturally adapted cognitive behavioural therapy, delivered individually or in groups by trained non-professional facilitators, can provide an acceptable, effective, and cost-efficient first-line treatment for postnatal depression in these populations. Future research should investigate the acceptance, effectiveness, and broader effects of online interventions, including their effects on children and families of women with depression.

or infant-to-mother), maternal withdrawal, maternal hostility, and developmental delays at school age.[4] In the UK, each case of perinatal depression incurs an estimated lifetime cost of £75 000, with two-thirds attributed to the child's adverse outcomes.[5]

In the UK, minority ethnic groups, particularly the British south Asian group, face a higher burden of mental disorders, including postnatal depression, compared with the White population.[6,7] Owing to cultural and language barriers, these conditions are less likely to be detected or treated in minority ethnic groups.[7,8] Primary care services are also less likely to recognise mental health symptoms in south Asian individuals, resulting in fewer referrals to specialist care.[7]

Although antidepressants are effective for treating postpartum depression, new mothers might hesitate to use them owing to concerns about side-effects for themselves and their babies.[9] Therefore, cognitive behavioural therapy (CBT) is recommended as a first-line treatment and has proven to be effective for postnatal depression.[9,10]

The ROSHNI-2 trial was a multicentre randomised controlled trial that tested the effectiveness of the Positive Health Programme (PHP), a culturally adapted group CBT, combined with treatment as usual versus treatment as usual alone in British south Asian women with postnatal depression.[11–13] The primary outcome was remission from depression, defined as a Hamilton Depression Rating Scale score of less than 8 at 4 months after random assignment. Further details of the trial are available in the published studies.[12,13]

Although several studies have assessed CBT's effectiveness in terms of depression remission, few have evaluated its cost-effectiveness in terms of quality-of-life

gains, particularly among minority ethnic groups.[14,15] Health economic evaluations estimate the relative costs and benefits of interventions and summarise these by the incremental cost-effectiveness ratio (ICER). In the UK, interventions are typically considered cost-effective if the ICER is less than £20 000–30 000 per quality-adjusted life year (QALY).[16] This study aims to assess the cost-effectiveness of PHP added to treatment as usual compared with treatment as usual alone in the ROSHNI-2 trial.

Methods

Study design and participants

This health economic evaluation was conducted for a multicentre, two-arm, rater-blinded, randomised controlled trial, with ethics approval from the Northwest Health Research Authority (Integrated Research Application System 187851). A detailed study protocol and the effectiveness of the PHP intervention have been reported elsewhere.[12,13] The prespecified economic analysis plan is available upon request. The methods and analyses for the economic evaluation follow CHEERS reporting guidelines and previous economic evaluation papers.[17,18] All procedures comply with the ethical standards of national and institutional human experimentation committees and the Helsinki Declaration.

For the **study protocol** see https://www.fundingawards.nihr.ac.uk/award/14/68/08

The trial was conducted in UK regions with large south Asian populations, including northwest England, Yorkshire, East Midlands, and London. The inclusion criteria comprised: British south Asian women aged 16 years or older, with a child aged up to 12 months, and meeting DSM-5 criteria for depression. The exclusion criteria comprised: a diagnosed physical or intellectual disability preventing informed consent, postpartum or other psychosis, and active suicidal ideation. Baseline assessments were completed within 6–8 weeks of random assignment, with follow-ups completed at 4 months after randomisation (end of PHP intervention) and 12 months. Full details are provided in the published protocol.[12]

In terms of patient and public involvement, the project included a co-applicant with lived experience who contributed to selecting processes, methods, and measures, and supported dissemination and impact activities. A service user researcher provided lived experience input into developing methods and measures. Health economics measures were shaped by insights from community, family, and faith leaders.[13]

Intervention

The PHP intervention comprised 12 group sessions delivered by two trained bilingual facilitators over 4 months. The PHP focused on identifying the pressures of being a south Asian mother, the ABC model of depression, religion and spirituality, managing self-esteem, exercise, relaxation, assertiveness and confidence, reducing social isolation, building social networks, and developing relapse prevention plans. Facilitators, National Health Service (NHS) band 4–6 researchers with degrees in psychology, social science, or related fields, completed a 2-day train-the-trainer course. Sessions were held once per week for the first 2 months and once per fortnight thereafter, with each session lasting 60–90 min. The PHP manual was available in English and the participants' preferred languages (including Urdu, Bengali, Gujarati, Punjabi, Hindi, and Tamil) with facilitators matched to the group's language preferences. PHP supervisors attended one to two sessions to ensure fidelity. Sessions were delivered at children's centres and other neutral community venues, based on participant preference.

All participants had access to treatment as usual, typically accessed through general practitioner services. They received primary care management for postnatal depression and were referred to other social or secondary care services as needed, including routine appointments, NHS Talking Therapies (formerly Improving Access to Psychological Therapies) for anxiety and depression, antidepressant prescriptions, and traditional healing services such as engagement with community and faith healers. The primary outcome measure for clinical effectiveness, reported elsewhere,[13] was remission or recovery from depression post-intervention, defined by a Hamilton Depression Rating Scale (HDRS) score of 7 or lower at 4 months.

Data collection

Costs and outcomes were gathered from all participants via self-administered questionnaires at baseline and follow-ups, facilitated by masked assessors. For the cost-utility analysis, the outcome was quality-adjusted life-years (QALYs) gained from baseline assessment to the 12-month follow-up. Health states were assessed using the three-level EuroQol 5-dimension measure of health-related quality of life (EQ-5D-3L), which is a widely used generic quality-of-life measure, delivered in the participants' preferred languages. The use of EQ-5D-3L was tested in this population during feasibility studies before the main trial and has been used in previous studies with these communities in both the UK and south Asia.[19–21] The UK general population tariff was applied to convert EQ-5D-3L scores into health utility values.[22] QALYs were calculated using time-weighted linear interpolation of utility scores at baseline, 4 months, and 12 months as follows:

$$QALY=[(U_{baseline}+U_{4\text{-months}})/2]\times 0\cdot 333+[(U_{4\text{-months}}+U_{12\text{-months}})/2]\times 0\cdot 677$$

where U stands for EQ-5D-3L utility score. The effect measure for cost-effectiveness was depression remission at 4 months, defined as per the main trial as an HDRS score of 7 or less.[13]

Resource use data were collected using a bespoke economic patient questionnaire, which incorporates questions from the Client Service Receipt Inventory and was used in previous mental health trials.[23] The economic patient questionnaire was adapted to align with the practices of this population through input from service users and community, and the team's research experience with south Asian populations.[19,24] The economic patient questionnaire covered community, primary, and secondary health-care use, as well as other social support services and health and care services (including traditional or religious healing services). These services encompassed both mental and physical health-related visits and admissions. Because most PHP sessions occurred in 2018 and 2019, the 2018–19 unit costs were applied for secondary, primary, and community health-care resources. Costs were calculated using standard figures from NHS England, NHS Improvement, and the Personal Social Services Research Unit publications (appendix p 2).

The costs of the PHP intervention included facilitator or therapist payments (for preparation, delivery, and travel), supervisor fees, venue hire, crèche services, catering, printing of materials, participant travel expenses, and facilitator training. More than half of the sessions were held in children's centres, which did not charge for using their space. However, because these centres had opportunity costs, we assigned the average cost of using community venues at the relevant study sites. Since the economic evaluation is from the health and social care sectors' perspective, the £10 paid per session to each participant in the PHP group was excluded from the base-case analysis.

Overall mean values (single imputation) were used for missing baseline data. For categorical demographic variables, a missingness indicator was created.[25] Missing cost and effect data at 4 months and 12 months were imputed using multiple imputations (50 imputations). The imputation model included the intervention indicator, baseline values of costs, utilities scores, HDRS scores, demographic indicators, and group and study site indicators.[25] The predictive mean matching algorithm was applied, and estimates from the imputed data were averaged using Rubin's rule.[25]

Data analysis

The cost-effectiveness of PHP was assessed using intention-to-treat analyses over the 12-month trial horizon, from the perspective of the NHS and personal social services. Data for the economic evaluation from a societal perspective were not collected due to possible cultural sensitivities around home production, unpaid adult care, and labour force participation (eg, home production and unpaid adult care are sometime viewed as religious or cultural duties), as well as to minimise the data collection burden. Previous studies have characterised these communities as hard to reach and sensitive about data sharing.[13,20]

The differences in costs and effects between PHP and treatment as usual were calculated using regression analysis. Incremental costs were estimated using a γ-distributed generalised linear model with a log-link, whereas incremental effects were estimated with a β-distributed generalised linear model with a logit-link to handle skewed data (right-skewed costs and left-skewed QALY distributions).[26] Similar to the clinical efficacy study, the models included intervention indicator, baseline cost, EQ-5D-3L utility score, age, qualifications, and study stratification indicators as fixed effects and PHP group indicators as random intercepts, with treatment as usual participants treated as clusters of size one, to account for the within-PHP-group clustering.[13,26] Cost and effect regressions were jointly estimated in Stata 17.0 using the Generalised Structural Equation Modelling suite of commands, with regression errors treated as independent. However, cost and effect equations were interdependent due to shared random intercepts, covariates, and the fact that Generalised Structural Equation Modelling jointly maximises the likelihood function.[26]

See Online for appendix

Uncertainty was addressed by extracting 10 000 non-parametric bootstrapped samples.[16,18] For each sample, we calculated incremental costs, incremental effects, and the incremental cost-effectiveness ratio (ICER), which indicates the mean additional cost in the PHP arm to produce one extra effect (QALY or remission from depression) compared with treatment as usual only. The incremental costs and incremental effects of the 10 000 bootstrapped samples were plotted on cost-effectiveness planes, displaying the differences in costs and effects between PHP and treatment as usual only. Cost-effectiveness acceptability curves were drawn based on the distribution of the ICERs on the cost-effectiveness planes. Cost-effectiveness acceptability curves show the likelihood that PHP is more cost-effective than treatment as usual only as a function of the willingness to pay for one additional QALY or remission. For the cost-utility analysis, the UK National Institute of Health and Care Excellence (NICE) willingness-to-pay threshold of £20 000–30 000 per QALY was used.[16] Since the willingness to pay for remission from depression is not established, we started with a willingness to pay value of zero, gradually increasing it until the likelihood of PHP effectiveness approached nearly 100%.[18]

Stratified analyses compared the incremental costs, effects, and ICERs of online or partly online and in-person sessions to treatment as usual only. This was a post-hoc analysis focusing on the online sessions that began in March, 2020, after the onset of the COVID-19 pandemic. Although not a robust economic evaluation, these analyses were added to offer an early indication of the potential for online PHP delivery and the likely success of a future large-scale evaluation.

Sensitivity analyses included: (1) complete case analysis; (2) complier average causal effects; (3) adding a £10 attendance cost per session to PHP delivery costs; (4) varying the published unit costs of health and social care by ±10%; (5) linear regression instead of generalised linear regressions; (6) introducing two deviations from the missing-at-random assumption used for imputing missing data; and (7) multiple imputations of missing baseline data. All of these sensitivity analyses were pre-planned, except the multiple imputation of missing baseline data which was added post-hoc after review.[27] These analyses examined the sensitivity of the base-case results to changes in key variables, such as missing data, violations of the missing-at-random assumption used for imputation, regression functional form specification, and any discrepancies between the actual and published national average unit costs of health-care resources. The complier average causal effects analysis assessed the actual causal effects of the therapy on those who attended at least one session, compared with the intention-to-treat analysis in the base case.

For the complier average causal effects analysis, as in the clinical efficacy study, compliance was defined as attending at least one PHP session.[13] The randomisation indicator was used as an instrument for the binary compliance indicator to estimate three-stage least-squares seemingly unrelated regression.[28]

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

From Feb 8, 2017, to March 29, 2020, 732 eligible women were enrolled: 368 participants were randomly assigned to the PHP arm and 364 to the treatment-as-usual arm. The participants were divided into 42 groups: 21 from the northwest of England, three from Yorkshire, three from the East Midlands, and 15 from London. The average group size was 18 participants, evenly split between the PHP and treatment-as-usual arms. At the 4-month follow-up, 297 (81%) participants in the PHP arm and 301 (83%) participants in the treatment-as-usual arm had completed all questionnaires. At 12 months, 220 (60%) participants in the PHP arm and 230 (63%) participants in the treatment-as-usual arm had provided data.

The mean age was 31·4 years (SD 5·2) and was similar between arms.[13] Of the 719 participants with ethnicity data, 397 (55%) were Pakistani, 176 (24%) Indian, 127 (18%) Bangladeshi, and 19 (3%) from other south Asian backgrounds. Of the 722 participants with language preference data, 316 (44%) preferred English, 232 (32%) Urdu, 71 (10%) Bengali, 51 (7%) Punjabi, 30 (4%) Gujarati, 4 (1%) Hindi, and 15 (2%) other languages.[13] Among 701 participants reporting qualifications, 26 (4%) had

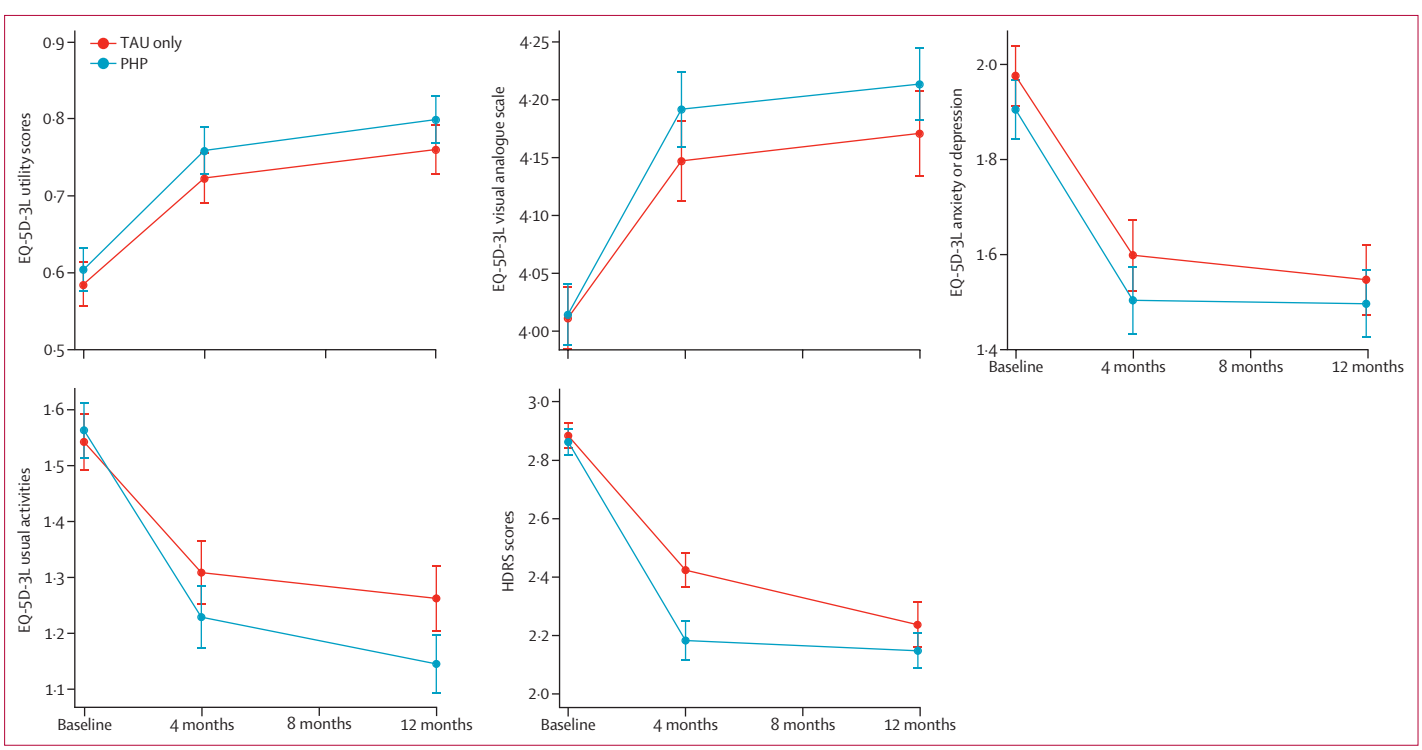

Figure 1: **Adjusted health-related quality of life and depression scores (based on multiple imputations)**
All plots are based on predicted values, adjusted for age, qualifications, study centre, and random intercepts at the PHP group level. EQ-5D-3L=three-level EuroQol 5-Dimension generic measure of health-related quality of life. HDRS=Hamilton Depression Rating Scale. PHP=Positive Health Programme. TAU=treatment as usual.

primary schooling, 117 (17%) GCSEs, 150 (21%) A-levels, 221 (32%) a first degree, 119 (17%) a higher degree, and 68 (10%) had other qualifications.[13] The mean number of PHP sessions attended per person was 6·01 (95% CI 5·54–6·47). Of the 368 PHP arm participants, 92 (25%) attended no sessions, 50 (14%) attended one to four sessions, 72 (20%) attended five to eight sessions, 154 (42%) attended more than eight sessions, and 35 (10%) attended all 12 sessions.

The estimated cost of the PHP programme was £4063 per group and £463 per person. The main cost was facilitator pay (£1100 per group, £125 per participant), based on NHS bands 4, 5, and 6 for 2·5 h per session (preparation and delivery). The next largest costs were for crèche services (£1002 per group), venue hire (£537 per group), participant travel (£513 per group), catering (£392 per group), PHP supervisor pay and travel (£152 per group), and facilitator travel (£142 per group). Additional costs included facilitator training (£6622 total) and printing PHP manuals and training materials.

The mean health-care costs and EQ-5D-3L health states are reported in the appendix (pp 3–7). Unadjusted mean health and social care utilisation costs were £608 per participant in the PHP arm and £596 in the treatment-as-usual arm at baseline, and £274 versus £264 at the 12-month follow-up (appendix pp 3–4). Secondary care was the primary source of health-care costs in both arms, primarily for physical reasons (appendix p 5). At baseline, mean elective inpatient days were 0·11 in both the PHP and treatment-as-usual arms, mean number of outpatient appointments was 0·10 and 0·11, and mean number of emergency visits was 0·06 and 0·07, respectively. During the trial period (1–12 months), mean elective inpatient days were 0·04 for both arms, whereas the mean number of outpatient appointments increased to 0·27 in the PHP arm (0·17 in the treatment-as-usual arm), and the mean number of emergency visits per participant was 0·09 versus 0·06, respectively. At baseline, mean general practitioner visits per participant were 1·10 in the PHP arm and 1·07 in the treatment-as-usual arm, compared with 0·92 and 0·89 during the trial period. Community-based mental health service use was minimal in both arms (0·01 per participant). Other health and social support use was relatively higher, with a mean of 0·09 in the PHP arm versus 0·05 in the treatment-as-usual arm at baseline, and 0·13 in the PHP arm versus 0·10 in the treatment-as-usual arm during the trial period, suggesting the use of traditional healing services (appendix p 5). Overall, during the trial period (1–12 months), the unadjusted mean health-care costs were £784 (95% CI 581–1013) in the PHP arm and £636 (495–791) in the treatment-as-usual arm.

During the trial period (1–12 months), the mean unadjusted QALYs were 0·747 (95% CI 0·729–0·764) in the PHP arm and 0·713 (0·692–0·733) in the treatment-as-usual arm. The adjusted quality-of-life and depression scores, accounting for all covariates included in the main analysis, are presented in figure 1. Health-related quality of life, measured by the 3-level EuroQol 5-dimension (EQ-5D-3L), was higher in the PHP arm than in the treatment as usual arm, but utility scores were not statistically significant at any time point (figure 1). However, the PHP arm showed a significantly better health-related quality of life in the usual activities dimension at the 12-month follow-up (figure 1). A notable difference in remission from depression was observed at the 4-month follow-up (figure 1), although this difference was not statistically significant by 12 months. Further details on the EQ-5D-3L health states are presented in the appendix (pp 6–7).

The adjusted differences in costs (health-care use and PHP delivery) and effects between the PHP intervention and treatment-as-usual arms from health and social care perspectives are presented in table 1. In the intention-to-treat analysis, the PHP resulted in a significant cost increase (£712, 95% CI 311–1113) and a QALY gain of 0·036 (95% CI 0·006–0·067) over 12 months (table 1). The mean difference in remission rates at 4 months was 0·126 (0·049–0·203), with a corresponding mean cost difference of £692 (283–1101).

The analysis yielded a mean ICER of £19 601, indicating that gaining one additional QALY with PHP versus treatment as usual alone is associated with a cost of £19 601 (95% CI 7622–83 772, based on 10 000 bootstrapped replications). Remission in postnatal depression (Hamilton Depression Rating Scale score of ≤7) at the 4-month follow-up resulted in an ICER of £5509 (2916–17 860) based on the 10 000 bootstrapped samples.

The bootstrapped incremental costs and effects were used to generate cost-effectiveness planes and cost-effectiveness acceptability curves. The first panels in figures 2 and 3 show the cost-effectiveness planes for the base-case of the cost-utility and cost-effectiveness analyses, plotting costs against effects. The uncertainty

	Incremental cost (95% CI)	Incremental effect (95% CI)	ICER (95% CI)
QALYs, adjusted incremental differences*	£712 (311 to 1113)	0·036 (0·006 to 0·067)	£19 601 (7622 to 83 772)
Remission, adjusted incremental differences*	£692 (283 to 1101)	0·126 (0·049 to 0·203)	£5509 (2916 to 17 860)
In-person and online *vs* treatment as usual*			
Zero sessions	£771 (327 to 1214)	0·003 (–0·040 to 0·046)	£205 568†
In-person sessions	£784 (404 to 1163)	0·035 (0·002 to 0·069)	£22 295 (7678 to 156 689)
Online sessions	£25 (–512 to 563)	0·125 (0·048 to 0·203)	£202 (–3906 to 10 918)

All incremental cost and effect analyses are based on multiple imputation data, adjusted for baseline cost, effects, qualifications, age, and study centre, and include random intercepts at the PHP group level. The 95% CIs for ICERs are constructed from 10 000 bootstrapped replications (200 replications per multiple imputation dataset). ICER=incremental cost-effectiveness ratio. PHP=Positive Health Programme. QALY=quality-adjusted life year. *Multiple imputation. †For the ICER of the zero sessions, 95% CIs are not reported because, as shown in figure 4, 43% of replications fall in the top left quadrant (higher cost and lower effectiveness), where negative ICER values are misleading.

Table 1: **Differences in costs (2018–19) and effects between PHP plus treatment as usual versus treatment as usual only over 12 months**

in the ICERs was predominantly driven by uncertainty in incremental costs (figures 2 and 3). In figure 2, 99% of replications fell in the top right quadrant, indicating that PHP was more effective in improving QALYs and was more costly in 99% of samples. In figure 3, nearly all replications fell in the top right quadrant, showing that PHP was more effective in achieving remission from depression, but at a higher cost in all samples compared with treatment as usual alone.

The second panels in figures 2 and 3 show cost-effectiveness acceptability curves, illustrating the probability of PHP being more cost-effective than treatment as usual alone at different willingness-to-pay thresholds for one additional QALY or remission from depression. At the lower bound of the NICE threshold of £20 000, the probability of PHP being cost-effective in generating an additional QALY was 53%, increasing to 77% at the upper bound of NICE's threshold of £30 000 per QALY (figure 2). In figure 3, the probability of PHP being cost-effective in achieving remission from depression exceeded 50% at a willingness-to-pay threshold of £5500 and reached 90% at £10 000.

For the stratified analysis, the PHP arm was divided into those who attended no sessions (92), attended all sessions in person (242), or attended most or all sessions online (referred to as the online group; 34). In the online group, 17 participants attended only online sessions, and the other 17 attended a mean of 8·24 sessions, with 6·94 of them being online sessions. The mean cost per person for online delivery of the sessions was £289, compared with £463 overall. The 34 participants attending online sessions showed greater, sustained quality-of-life improvements than those attending in person (appendix p 1). This difference is unlikely to be due to session attendance, because the in-person group attended 8·06 mean number of sessions compared with 7·62 in the online group.

To assess the cost implications of all or partial online delivery, we compared participants in each category with the treatment-as-usual arm using 10 000 non-parametric bootstrapped samples to estimate uncertainty around ICERs. In-person sessions resulted in an ICER of £22 295 (95% CI 7678 to 156 689). For the online group, there was a non-significant cost increase of £25 (95% CI –512 to 563) and a significant QALY gain of 0·125 (95% CI 0·048 to 0·203), with an ICER of £202 (–3906 to 10 918) per QALY. The probability of PHP being cost-effective exceeded 50% at negligible costs and reached 100% at less than the £20 000 threshold for those receiving online sessions during the COVID-19 pandemic (figure 4).

Several sensitivity analyses were conducted to test the robustness of PHP's cost-effectiveness (table 2), with ICERs estimated from 5000 non-parametric bootstrapped samples. Complete case analysis (59% of participants) resulted in a higher ICER of £23 592 (95% CI 10 253–338 046). However, the data were not missing completely at random. Complier average causal effects analysis gave a lower ICER of £17 749 (2219–73 802).

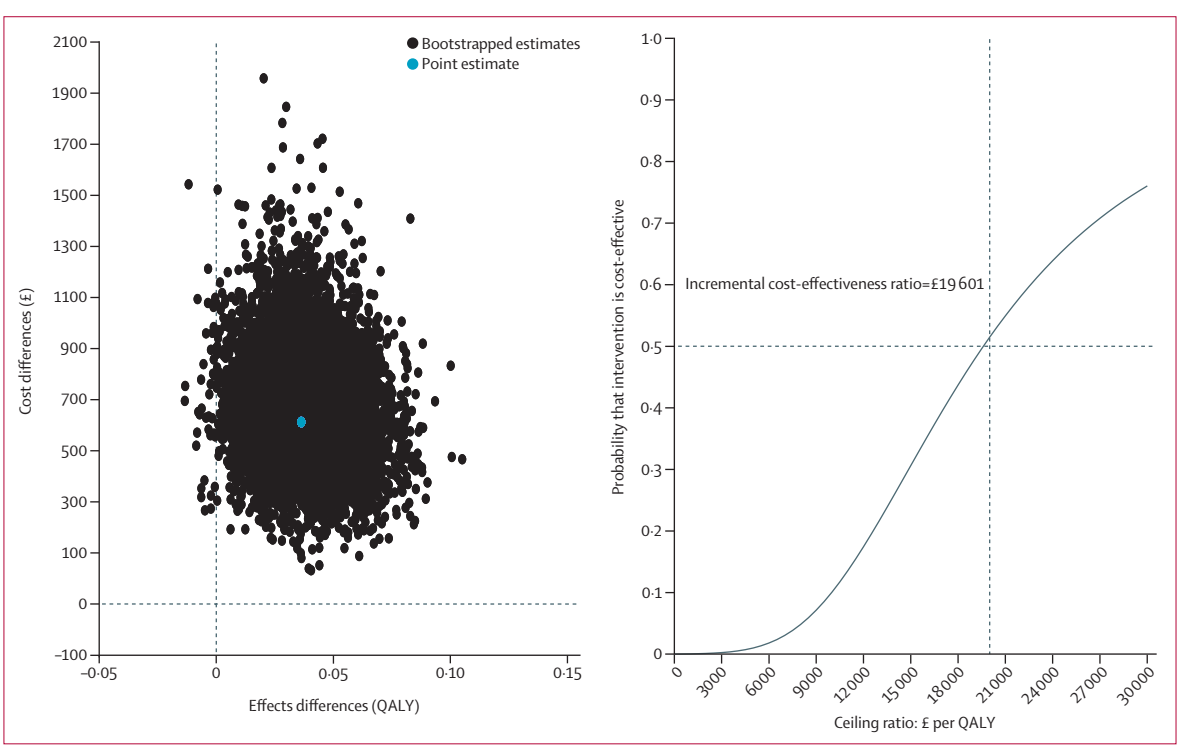

Figure 2: **Cost-effectiveness plane and cost-effectiveness acceptability curve (outcome: QALYs)**
QALY=quality-adjusted life-year.

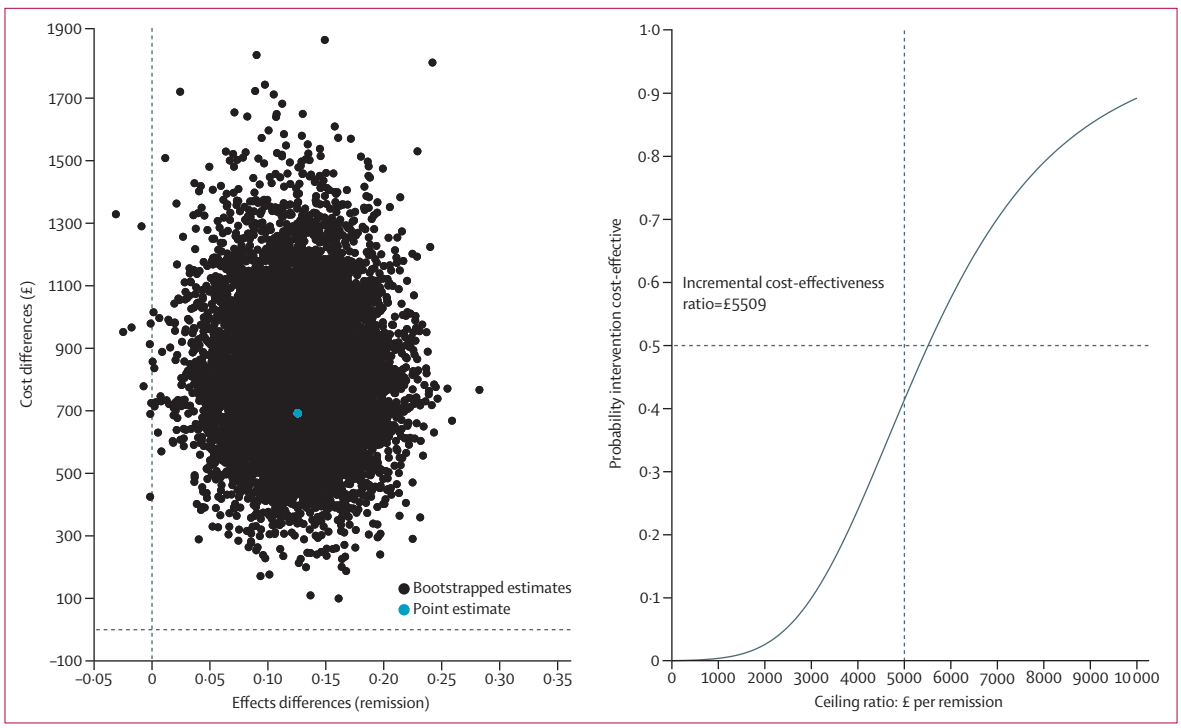

Figure 3: **Cost-effectiveness plane and cost-effectiveness acceptability curve (outcome: remission)**

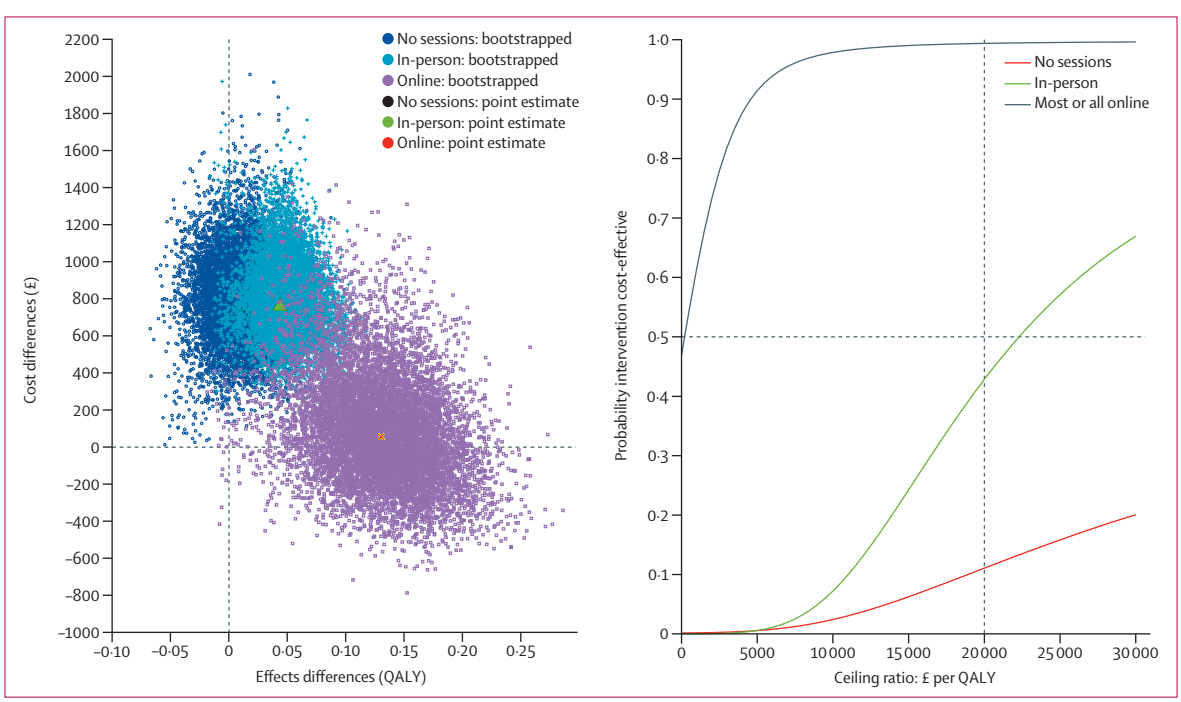

Figure 4: **Cost-effectiveness planes and cost-effectiveness acceptability curves for in-person and online sessions versus the control arm (outcome: QALYs)**
QALY=quality-adjusted life-year.

To test assumptions about missing data, two adjustments were made to multiple imputations.[27] In the worst-case scenario (costs 10% higher and utility scores 10% lower than the model-predicted missing values), the ICER was £21429 (95% CI 7937–103936; table 2). In the best-case scenario (the reverse), the ICER was £17654 (7192–68883). Reducing all health and social care unit costs by 10% compared with the published unit costs produced an ICER

	Incremental cost 2018–19 (95% CI)	Incremental QALYs (95% CI)	ICER (95% CI)
Complete cases (429 [59%] of 732 participants)	£700 (422 to 978)	0·030 (–0·016 to 0·078)	£23 592 (10 253 to 338 046)
Worst-case missing data scenario	£728 (305 to 1151)	0·034 (0·005 to 0·063)	£21 429 (7937 to 103 936)
Best-case missing data scenario	£713 (320 to 1106)	0·040 (0·008 to 0·073)	£17 654 (7192 to 68 883)
10% lower health-care unit cost	£700 (329 to 1071)	0·036 (0·006 to 0·067)	£19 282 (7591 to 84 499)
10% higher health-care unit cost	£724 (295 to 1153)	0·036 (0·006 to 0·067)	£19 929 (7223 to 88 293)
CACE	£761 (281 to 1241)	0·043 (0·007 to 0·078)	£17 749 (2219 to 73 802)
Linear model	£631 (316 to 946)	0·026 (–0·004 to 0·055)	£24 374 (7503 to 271 479)
With PHP attendance costs	£788 (401 to 1174)	0·036 (0·005 to 0·067)	£21 691 (8929 to 90 582)
Multiple imputation of baseline missing data	£673 (292 to 1054)	0·033 (0·003 to 0·062)	£20 573 (7474 to 98 478)

Except for the first row, all results are from multiple imputation data. In the worst-case scenario, missing health-care use costs were 10% higher and health states were 10% lower than the multiple imputation models. The best-case scenario was the opposite of worst-case scenario. All analyses controlled for baseline cost, utility score, qualifications, age, study centre, and include random intercepts at the PHP group level. The 95% CIs for ICERs are constructed from 5000 bootstrapped replications (with 100 replications per multiple imputation dataset). For the complete cases, the 95% CI for the ICER is constructed from 5000 bootstrapped replications of incremental cost and effects. CACE=complier average causal effects. ICER=incremental cost-effectiveness ratio. PHP=Positive Health Programme. QALY=quality-adjusted life year.

Table 2: **Sensitivity analyses**

of £19 282 (7591–84 499). Increasing health and social care unit costs by 10% produced an ICER of £19 929 (7223–88 293). Compared with table 1, the ICER increased to £24 374 (95% CI 7503–271 479) using linear regression models (table 2). Adding session attendance costs (£10 per session) raised the ICER to £21 691 (8929–90 582). Finally, when baseline missing cost and health state data were imputed using multiple imputation instead of single imputation, the ICER remained £20 573 (474–98 478). Thus, most sensitivity analyses were less than or within NICE's £20 000–30 000 range.

Discussion

This analysis suggests that the PHP programme leads to higher QALYs (mean difference 0·036; 95% CI 0·006–0·067) and costs (mean difference £712; 311–1113) compared with treatment as usual alone, translating to a cost of £19 601 (7622–83 772) per QALY gained. The ICER of £19 601 per QALY is near the lower boundary of the £20 000–30 000 per QALY willingness-to-pay thresholds used by NICE, with a 53% likelihood of PHP being cost-effective at £20 000 and 77% at £30 000 compared with treatment as usual alone. Although not cost-saving, PHP could be a cost-effective intervention at the NICE willingness-to-pay threshold of £20 000–30 000 per QALY from the perspective of NHS and personal social services.

Each episode of perinatal depression in the UK is estimated to cost £75 000 over a lifetime for the mother and child, with two-thirds of this burden falling on the child.[5] Considering the cultural and linguistic needs of minority ethnic groups, PHP could serve as a cost-effective intervention for postpartum depression in women from minority ethnic groups. PHP effectively facilitated quick recovery from postnatal depression and improved parenting competence, which might lead to better child outcomes—benefits not included in this economic evaluation.[13,29,30] The difference in health-related quality of life between the PHP and treatment-as-usual arm participants not only persisted but also increased at the 12-month follow-up. Similarly, at 12 months, the PHP arm participants showed significantly higher Parenting Sense of Competence Scale scores as reported in the clinical efficacy paper[13] (adjusted difference 3·32; 95% CI 1·10–5·54), indicating a greater sense of competence in parenting compared with the control arm participants. This finding suggests that the benefits of PHP might extend beyond the mother and trial period, potentially further reducing the long-term cost per QALY gained.[15]

The PHP programme was interrupted by the onset of the COVID-19 pandemic, leading to a protocol change to deliver the remaining sessions online. The stratified cost-utility analysis indicated that the ICER for online sessions was just £202 per QALY, with a 100% likelihood of cost-effectiveness at a willingness-to-pay threshold of less than £15 000, suggesting that the online delivery of PHP might be a viable future option. However, these results are based on a small sample of 34 participants, limiting the robustness of the comparison. The potential clinical and cost-effectiveness of online PHP warrant further investigation in future studies. The better outcomes for those in the online PHP group might be due to participants learning to cope with isolation during the sessions or because pandemic restrictions reduced the positive effects of PHP for those who completed the programme earlier. Additionally, online delivery probably shifted some costs, such as childcare and catering, to participants, although these might be offset by reduced travel expenses and environmental benefits.

Interviews revealed that participants preferred in-person sessions over online sessions for better confidentiality, group interaction, and to avoid connectivity issues. Nonetheless, many valued the flexibility of remote delivery, particularly those whose household responsibilities had previously hindered in-person attendance, and they felt that PHP helped them navigate the challenges of lockdown.[13] Given the mixed preferences and the fact many people from minority ethnic groups live in joint families with care-giving duties, a blended (ie, partly in-person and partly online) PHP intervention could enhance participation and cost-effectiveness in the future.[31]

Camacho and Shields[32] reported on eight studies assessing the cost-effectiveness of interventions for the prevention, treatment, or screening of postnatal depression. These studies evaluated various treatments, including access to psychiatric day hospitals, counselling, support from trained health visitors, CBT, and collaborative

care with psychiatrists. The interventions ranged from dominant (rare) to those costing more than £30 000 per QALY gained in 2015 sterling, with costs per recovery varying from net saving to as high as £56 865. Among 39 perinatal mental health interventions, Verbeke and colleagues[15] identified 21 studies on interventions for anxiety and depression in high-income countries, mostly from the UK and the USA, with only seven based on CBT or interpersonal therapy, or both. Of these, five included cost-utility analyses. In two studies, the intervention dominated treatment as usual, whereas in the others, the cost per QALY ranged from €8850 to €59 099. Although uniquely delivered by non-specialist workers to diverse ethnocultural groups, the QALY gains and cost per QALY for the PHP intervention aligned with those of similar interventions in the UK.

Unlike depression remission, the difference in health-related quality of life between the PHP and treatment-as-usual arms in the ROSHNI-2 trial was sustained at 12-month follow-up. This finding highlights the value of faster recovery from postnatal depression for participants and potentially for their infants and families.[13,33,34] Early intervention can prevent chronic depression, improve quality of life, enhance mother–infant bonding, and lead to better cognitive and emotional outcomes in infants.[29,30] Women who recover early are more likely to return to work, show improved productivity, have reduced absenteeism, and foster stronger family cohesion and stability.[3,35] The marked improvement observed in the usual activity dimension of EQ-5D-3L in figure 1 might be the manifestation of these advantages resulting from the PHP intervention. For example, the intervention led to a significant improvement in parenting sense of competence.[13] Quality parenting in early childhood is associated with positive mental and physical health outcomes and financial benefits over the lifespan.[36]

The PHP intervention focused on developing assertiveness skills and enhancing participants' confidence and communication, as well as reducing social isolation through new relationships and social networks. These new developments could help alleviate the fear of stigma, leading to increased health-care use and reporting.[7,8,37] Existing evidence indicates a clear negative association between mental health-related stigma or stigmatising attitudes and help-seeking among individuals.[38] Similarly, group-level anti-stigma interventions have shown at least short-term benefits in combating stigma and discrimination related to mental illnesses.[39] If so, the cost per QALY gain from the PHP could be overestimated.

This study has several limitations. EQ-5D-3L responses were converted into QALYs using a value set for the general UK population, because no ethnicity-specific value set is available. Resource use data were collected through a patient questionnaire, which might introduce recall bias. The study assumes that the monetary and non-monetary engagement efforts during recruitment to the trial[13] did not differentially affect participants in the two arms, attributing all cost and effect differences to the PHP intervention. Only 59% of participants had complete data, potentially introducing bias. However, introducing 10% deviations on either side of the model-predicted values for the missing data suggested that any bias due to missing data was minimal. Participants were not masked to treatment allocation, which might have led to strategic behaviour in reporting costs and health-related quality of life, introducing further bias. Cost-effectiveness analyses could not be conducted from family or societal perspectives. Finally, the ROSHNI-2 trial focused exclusively on British south Asian women, limiting the generalisability of findings to other minority ethnic groups.

This study provides evidence that the PHP programme, combined with usual care, might be a cost-effective alternative to the standard of care for treating depression and improving quality of life among British south Asian women with postnatal depression, provided policy makers are willing to pay £20 000–30 000 per QALY gained. Further research is required to evaluate the effectiveness and cost-effectiveness of online delivery of such therapies and their broader effect on children and family outcomes.

Contributors

AU, FL, and DS drafted the paper, and all other authors critiqued the manuscript for important intellectual content. NH was the study chief investigator with overall responsibility for the study and the decision to submit for publication. AU was responsible for the health economics component of the project including full analysis and write-up of this manuscript. FL was the trial manager and responsible for delivery and management of the project and representative of the sponsor National Health Service (NHS) organisation. FL and DS were involved in recruitment and engagement of participants and delivery of the Positive Health Programme (PHP) intervention. RM and TB were responsible for the delivery of the project within the East Midlands sites. KB was a co-lead for the London sites. KB, AR, PB, and RM contributed in an advisory capacity to the conceptualisation, design, and interpretation of study findings. FL, MP, and AU accessed and verified the data for the analysis. All authors had full access to all the data used in the study, including statistical reports and tables, and take responsibility for the integrity of the data, the accuracy of the analysis, and the decision to submit for publication.

Declaration of interests

NH previously served as trustee of the Pakistan Institute of Living and Learning, Abaseen Foundation UK, Lancashire Mind UK, and Manchester Global Foundation; and is an executive member of the Academic Faculty at the Royal College of Psychiatrists, London. All other authors declare no competing interests.

Data sharing

Reasonable requests for patient-level data should be made to the corresponding author and will be considered by the ROSHNI-2 trial management group. The ROSHNI-2 management team and sponsor will consider the sharing of data on a case-by-case basis in line with the ethics approval and patient information sheets. Any presented data do not contain any direct identifiers.

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Appendix E - academic peer reviewed publications

List of all publications co-authored by myself including those in the portfolio**.**

1. Khan, S., Lovell, K., **Lunat, F**., Masood, Y., Shah, S., Tomenson, B., & Husain, N. (2019). Culturally adapted cognitive behavioural therapy-based intervention for maternal depression: A mixed-methods feasibility study. *BMC Women's Health, 19*(1), 21.
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3. Masood, Y., Lovell, K., **Lunat, F**., Atif, N., Waheed, W., Rahman, A., Mossabir, R., Chaudhry, N., & Husain, N. (2015). Group psychological intervention for postnatal depression: A nested qualitative study with British South Asian women. *BMC Women's Health, 15*(1), 109.
4. Husain, N., Zulqernain, F., Carter, L. A., Chaudhry, I. B., Fatima, B., Kiran, T., Chaudhry, N., Naeem, S., Jafri, F., **Lunat, F**., Haq, S. U., Husain, M., Roberts, C., Naeem, F., & Rahman, A. (2017). Treatment of maternal depression in urban slums of Karachi, Pakistan: A randomized controlled trial (RCT) of an integrated maternal psychological and early child development intervention. *Asian Journal of Psychiatry, 29,* 63-70.
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8. Husain, N., Lovell, K., Chew-Graham, C., **Lunat, F**., McPhillips, R., Atif, N., ... & Morriss, R. (2022). Multicentre randomized controlled trial of a group psychological intervention for postnatal depression in British mothers of South Asian origin (ROSHNI-2): Study protocol. *BJPsych Open, 8*(1)
9. **Lunat, F**., Islam, A., Ahmed, F., Begum, J., Aseem, S., Lorgat, M., Bhatti, H., Masood, T., Zaidi, N., & Husain, N. (2020). ROSHNI-2: Using a culturally adapted model of recruitment, engagement and retention to mental health research for British South Asian women experiencing symptoms of postnatal depression. *International Society for the Study of Behavioural Development, 2020 Bulletin, 1,* serial 77.
10. Hilton, C., Morris, A., Burnside, G., Harris, R., Aggarwal, V. R., Procter, S…..,**Lunat F**... & Palmier-Claus, J. (2023). A two-arm, randomised feasibility trial using link workers to improve dental visiting in people with severe mental illness: a protocol paper. *Pilot and Feasibility Studies, 9(1),* 157.
11. Husain, N., Kiran, T., Chaudhry, I. B., Sultan, S., Dawood, S., **Lunat, F**., ... & Chaudhry, N. (2023). Integrated Moving on After Breast Cancer and Culturally Adapted Cognitive Behavior Therapy intervention for depression and anxiety among Pakistani women with breast cancer: Protocol of a randomized controlled trial. *SAGE Open Medicine*, *11*, 20503121231177549.

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15. Memon, R., Shah, B.A., Asif, M., Eylem-van Bergeijk, O., Jidong, D.E., Ike, T.J., Khoso, A.B., Kiran, T., Omar, N., **Lunat, F**. and Miah, J., (2025). Accommodating cultural differences in the International Conference of Harmonisation Good Clinical Practice guidelines. *Journal of Medical Ethics.*
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18. Palmier-Claus, J., Morris, A., French, P., Griffiths, R., Aggarwal, V. R., Berry, K.,**Lunat F** ... & Burnside, G. (2025). A Link Work Intervention to Facilitate Dental Visiting in People With Severe Mental Illness: A Two-Arm, Multi-Site, Assessor Blind, Randomised Feasibility Trial With Dental Record Linkage. *Community Dentistry and Oral Epidemiology*, *53*(5), 580-586.