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Mental health prevention and promotion in general practice settings: A protocol for a feasibility study

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ABSTRACT

Background: A reactive approach is typically taken when addressing and intervening with mental health problems rather than a proactive or preventative one, yet preventative approaches can also reduce mental ill-health. This study protocol aims to evaluate the feasibility of recruiting general practice patients into a randomised feasibility study where they will receive either mental health treatment as usual or a brief psychological intervention for preventing the deterioration of mental health and promoting emotional wellbeing.

Methods: This is a two-arm RCT, where participants will be randomised to either: treatment-as-usual within GP; or treatment-as-usual within GP plus a mental health prevention and promotion intervention. Sixty patients, aged 16+ from GP surgeries, with mild to moderate mental health difficulties as indicated by the PHQ9 and GAD7 will be recruited. Data on engagement with the intervention will be summarised using descriptive statistics. Regression models will be fitted, using the 12-week post-intervention follow-up data as the outcome variable and age, gender, trial arm and the corresponding baseline data as covariates. Cost-effectiveness will be investigated in an explorative way. Descriptive statistics will be used to analyse participant's resource use and HRQoL. Qualitative data will understand factors that facilitate or challenge the successful implementation of interventions and a process evaluation will provide insight into the intervention's mechanisms of action.

Discussion: The research team will progress from a feasibility RCT to a larger definitive RCT and disseminate widely across stakeholders (clinical, academic, service users, caregivers, Integrated Care Board (ICB) colleagues), ensuring accessibility in collaboration with the PPI committee.

1. Introduction

By 2026, the cost of mental health problems to the National Health Service (NHS) is predicted to rise to unaffordable levels if support arrangements remain unchanged (Knapp & McDaid, 2011). In 2022, The Mental Health Foundation (7-SAP) reported that poor mental health costs the UK £118 billion per year, of which £1.4 billion in General Practice, but much of it is preventable (McDaid & Park, 2022).

The King's Fund has stated in the 'Five Year Forward View' (The King's Fund, 2016) a need for a radical upgrade of disease prevention and public health promotion in regard to the sustainability of the NHS. Further to this, Public Health England aims to encourage an equal recognition of mental health prevention alongside programmes seeking to reduce smoking and obesity outlined in 'The Prevention Concordant for Better Mental Health' (GOV UK, 2023)', as physical health has historically been prioritised and receives greater funding (Mind., 2019). These messages have been reiterated in the recent NHS Workforce document outlining the need to equip the NHS workforce with the necessary skills and knowledge to shift care towards prevention and early intervention (NHS England, 2023).

Notably, The Mental Health Foundation issued a stark warning that when we fail to prevent people experiencing a deterioration in their mental health, life years are lost, and lives are damaged (Prevention Revolution, 2019). Traditionally, mental healthcare providers have taken a reactive approach in addressing and intervening with mental health problems rather than taking a proactive or preventative one. Yet,

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reviews and meta-analyses suggest that psychological preventive interventions can reduce mental ill-health (Cuijpers et al., 2008; Enns et al., 2016; Forsman et al., 2011; Garcia-Campayo et al., 2015; Lee et al., 2012; Robert et al., 2010; Roberts et al., 2019; Rojas et al., 2019; Van Zoonen et al., 2014; McDaid & Park, 2022). However, there is a need for more research in this area, as stated by the Department of Health and Social Care in indicating that "funding programmes should encourage research at the periods during which mental health problems can be prevented" (Department of Health & Social Care, 2017).

General Practice has the potential to be an excellent place to engage in preventative work, partly due to the frequency with which nearly all of the local community access the service and partly due to its non-stigmatising nature. However, a recent literature review (Budd et al., 2021) highlights the dissonance between the recommended mental health preventative activities that should be occurring in General Practice and what is actually happening. In 2022, the same authors published results of a service evaluation of a mental health prevention and promotion service delivered in General Practice settings by psychological practitioners (Budd et al., 2022). Five-hundred patients were provided with a brief, menu-based mental health prevention and promotion intervention. Moderate-large effect sizes (d = 0.6–1.3) and clinically and statistically significant ($p<.001$) improvements in patients' anxiety, depression, emotional wellbeing and resilience scores were found from the first to the last session, and were still significant at the 4–6-week follow-up. Qualitative feedback from patients, GP staff and graduates about the intervention was positive (e.g. short waiting times and personalised sessions). These results show promise in terms of the feasibility, acceptability and effectiveness of the intervention. However, increased research rigour through a control group comparison and longer-term follow-ups is required for more robust conclusions to be drawn.

This feasibility study will take place across two Primary Care Networks (PCNs) in Lancashire. The North West Coast (NWC) has a higher than national average prevalence of common mental health disorders; despite this, there is a much lower proportion of people being recruited into mental health studies (NIHR Research for Social Care, 2022). There are many areas of Lancashire and South Cumbria where life expectancy is below the national average; risk factors include deprivation, unemployment, high crime rates and low educational attainment (NHS Digital, 2021).

1.1. Aims and research questions

Broadly, the aim is to evaluate the feasibility of recruiting general practice patients into a randomised feasibility study where they will receive either mental health treatment as usual or a brief, menu-based, psychological intervention for preventing the deterioration of mental health and promoting emotional wellbeing. If possible, the study will also collect information on the parameters required to inform a subsequent, larger, randomised controlled trial (RCT) that would evaluate the clinical and cost-effectiveness of the intervention.

Specific Research Questions:

1. Will patients registered with a GP, presenting with mild to moderate mental health difficulties, be willing to be randomised to a study investigating the feasibility and acceptability of introducing a brief mental health prevention and promotion intervention? We will observe 1) the ability to recruit participants into the study, and 2) the retention and attrition rates of participants who consent to participate in the study.
2. What are the potential processes (e.g. facilitators and barriers) for acceptability and delivery of this psychological intervention within a GP setting? We will gather 1) participant, 2) GP staff, and 3) clinician feedback in order to refine and optimise the intervention (and subsequent trial design).
3. What patient safety factors need to be considered in relation to the intervention and service procedures? We will attempt to understand if clinical and research staff can safely identify, share and manage risk-related information in a GP setting.
4. Is it feasible to collect the outcome data required to determine the clinical and cost-effectiveness of the psychological intervention (in a future, larger trial) in a GP setting? We will determine the ability to collect 1) clinical outcome data (participants' baseline and follow-up metrics), and 2) economic outcome data (participants' healthcare resource use).

2. Method

2.1. Study overview

To ensure clinical trials can answer questions about whether an intervention helps, it is first important to check that it is possible to recruit enough participants to take part and to keep them involved. This feasibility study will tell us whether a larger clinical trial of a mental health prevention and promotion intervention in general practice is possible.

This study aims to understand if mental health prevention and promotion can be successfully introduced into NHS GP settings. Developing a robust evidence-base will facilitate the actualisation of preventative mental healthcare, starting regionally in the North West Coast area and expanding nationally. The envisaged end-goal would be for all general practices in England to have access to effective mental health prevention and promotion input by a trained Band 4 or above psychological professional. It is hoped that this would reduce instances of mental health 'caseness', thus reducing distress and relieving pressure on both mental health services and General Practice.

Sixty participants aged 16+ from GP surgeries in Lancashire, with mild to moderate mental health difficulties, will be recruited. Selected randomly, half of these participants will receive the usual input from their GPs (10-minute appointments). The other half will be offered four weekly, 45-minute preventative mental health sessions, with a fifth follow-up appointment 4–6 weeks later. The sessions will involve working with the participant to understand their current difficulties (psychological assessment), completing a psychological formulation and then providing information, guidance and coping strategies. The sessions are personalised, using approaches informed by different psychological approaches to help patients care for their emotional wellbeing. People's anxiety, low mood, wellbeing and resilience will then be measured over 4-months.

2.2. Study population

2.2.1. Inclusion/ exclusion criteria

Inclusion criteria:

- Registered patient at one of the General Practice sites in Pendle West or Burnley East PCN.
- Score ≤14 on the GAD-7 and ≤15 on the PHQ-9 at screening.
- Aged 16 and above.

Exclusion criteria:

- Already supported by a mental health service/ engaged in therapy elsewhere.
- Have a formal diagnosis of a severe mental health difficulty, where it would not be possible to meet their needs with four sessions.
- Require support from crisis services.
- Have a moderate to severe learning disability, where their needs can only be met within a specialist service.

2.2.2. Recruitment and sample size

Recruitment will take place in two Primary Care Network (PCN) sites in Lancashire, Pendle West and Burnley East. According to the Office of National Statistics (ONS) data, in Pendle West, approximately 35 % of the local population identify as Asian British. In Burnley East, the corresponding figure is just over 10 % (Office of National Statistics, 2011), therefore participant recruitment aims to reflect this. To ensure accessibility for all prospective participants, suitable adaptations (e.g. access to translators, availability of material in multiple languages) will be available.

Participants can enter the study via three routes, outlined in Fig. 1 below. One route is to self-select after seeing promotional study material and contacting the study team (e.g., a poster advertising the research in a waiting room). The second relates to potential participants being identified by GP staff during routine appointments. The patient will be informed that the practice is supporting the study and an information leaflet will be provided. If the patient verbally consents, their contact details will then be shared via an 'EMIS Task' (electronic health record messaging system used within the GP surgery) to a member of the study team. The study team will then contact the interested individual to provide more information. Thirdly, an electronic health record search that codes individuals based on their presentation, may help identify potential participants that may be struggling with their mental health, who will then be contacted via text message to advertise the opportunity to take part in the study. Understanding the preferred routes of access/ how participants are recruited is an important aspect of this feasibility study.

The research team will regularly promote the study and assess how frequently reminders are needed and impact on referral rates. The study will be promoted to GP staff during Clinical team meetings, promotional posters will be placed in the waiting area, reception and in consulting rooms. The study team will utilise social media, newsletters, GP monitor screens and community venues to promote the study. In order to ensure opportunities for research participation are extended to diverse communities, the study team will translate promotional posters into the top three commonly spoken languages within the recruiting PCNs (Office for National Statistics, 2022).

The study will recruit $N = 60$ participants to the study (30 per trial arm). This target requires a rate of recruitment of 10 participants per month across the two PCNs (recruitment has been set at 6 months). This number has not been determined via a formal power calculation, but will be sufficient to estimate key parameters to inform a future definitive trial with an adequate degree of precision (Lancaster et al., 2002).

2.2.3. Randomisation

Randomisation to the intervention arm or to treatment as usual, on a 1-to-1 basis, will occur following the obtaining of consent and the baseline eligibility assessment. A randomised block design (with random block sizes of 4 or 6, themselves chosen at random), stratified by PCN, will be used. Implementation will be via the online software programme *SealedEnvelope.com*. An individual independent of the study team will inform an Assistant Psychologist on the study team of the patients' allocation. The study Statistician will be masked to participant treatment allocation.

2.3. Study design

2.3.1. Design

This a two-arm RCT, where participants will be randomised to either: treatment as usual within GP; or treatment as usual within GP plus a

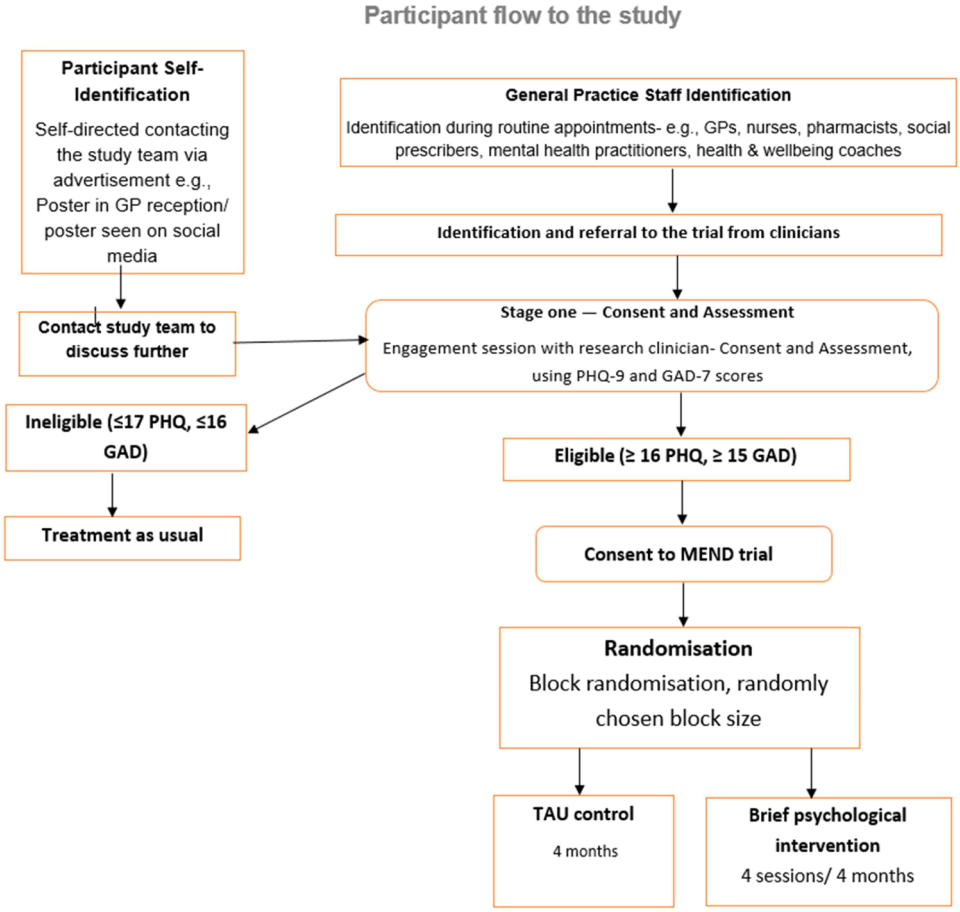

Fig. 1. Study flow diagram.

mental health prevention and promotion intervention.

2.3.1.1. Treatment as usual. Participants randomised to this arm will continue to receive mental health treatment as usual in general practice, accessing GP appointments as normal. Within these appointments, GP staff will be able to provide any usual form of mental health treatment, such as advice, medication or referral into another service. This feasibility study will collate data about the care each participant receives.

2.3.1.2. Prevention and promotion intervention. In addition to treatment as usual, patients allocated to the intervention arm will receive additional input through the prevention and promotion intervention. This is a brief one-to-one psychological menu-based intervention focusing on preventing mental health deterioration and promoting the importance of caring for one's emotional wellbeing. The intervention consists of four 45-minute appointments delivered weekly and has been designed in line with the Template for Intervention Description and Replication (TIDieR; BMJ, 2014). A fifth follow-up appointment will occur between 4 and 6 weeks later.

The intervention will be delivered face-to-face in the GP surgery or virtually, depending on participant preference. The intervention will be delivered by an Assistant Psychologist, who has undergone an intensive 6-weeks training. This training will be provided by qualified psychological professionals and focus on the principles and applications of different psychological techniques used in brief interventions. The Assistant Psychologists will also receive weekly individual clinical supervision for one-hour with a Consultant Clinical Psychologist. This supervision will ensure fidelity to the intervention model.

An outline of each session is as follows:

Session 1 – Psychological Assessment: Understand the patients' reasons for accessing support, current mental health and wellbeing and goals. Completion of a psychosocial assessment, including the outcome measures.

Session 2 – Psychological Formulation: Provide a psychological understanding of the patients presenting concerns; identifying factors causing, maintaining or alleviating the problem. Through shared decision-making, the patient and clinician will agree on the therapeutic focus of the remaining sessions and goals will be set. Psychological intervention can occur during the first and second session (for example, the provision of psychoeducation), but is the main focus of the third and fourth sessions.

Sessions 3 & 4 – Psychological Intervention: Teach the patient skills about how to look after their emotional wellbeing. These sessions are personalised to each patient's needs and informed by the approaches and tools adopted within (for example) cognitive-behavioural therapy, solution-focused therapy, motivational interviewing techniques and mindfulness. The clinician may also provide the patient with online resources, psychoeducation and/ or self-help worksheets. Please see Fig. 2 for an example of what the interventions may involve.

2.4. Patient and public involvement (PPI) and engagement

As part of the service evaluation completed (Budd et al., 2022), patients were offered four 45-minute appointments with a 45-minute follow-up appointment 4–6 weeks later. Sessions involved a psychological assessment, structured formulation and two intervention focused sessions, drawing on various psychological models. As a result, 240 Patient Experience Questionnaires were completed and analysed. A summative content analysis was conducted to identify themes. Almost all patients were both accepting of, and expressed benefiting from, the support they received. They reported liking the type of support provided, in terms of it being person-centred, helping them identify problem areas and build wellbeing skills. Additionally, patients were positive about accessibility, it being delivered within their local GP surgery. Constructive feedback highlighted a desire to increase the number of sessions.

In December 2021, a PPI involvement morning was held, supported by funding from the Research Design Service North-West (RDS NW). Four previous patients were invited to share feedback in more detail. This feedback helped to influence the research plan for this submission and the proposed intervention. Following on from this, a PPI member joined the research team and became a co-applicant.

The PPI team member has been involved in developing the protocol and supported with the care pathway such as reviewing the letters sent out to patients.

2.5. Ethics

Ethical approval has been granted from an NHS Research Ethics Committee (REC) and Health Research authority (HRA) (23/NW/0117) (IRAS: 323,448).

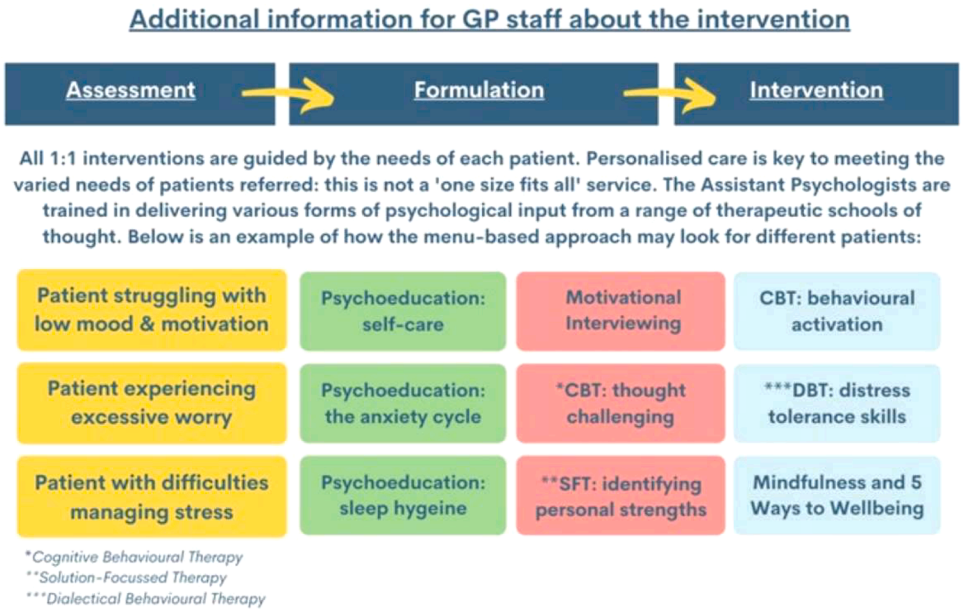

Fig. 2. Stages of intervention.

2.6. Outcomes

Demographics and equality and diversity monitoring information will be gathered at baseline; age, gender, first language, ethnicity, education level, employment status, postcode, income bracket, relationship status, disability, history of mental health and whether they have previously accessed mental health services.

The following data will be collected relating to feasibility, acceptability & safety (primary outcomes):

- Monthly recruitment rate (referred, consented, randomised) and participant flow (e.g. participant drop out).
- Intervention engagement (e.g. participant session attendance) and acceptability to both the participant and general practice staff.
- Completeness of clinical assessments (questionnaires).
- Frequency of reporting of patient risk and safeguarding incidents.

In addition, assessments of anxiety, depression and well-being (clinical outcomes) along with generic health status and health care utilisation will be collected at up to five points in time (see Table 1 below). Such outcomes will be considered as secondary to the more logistical outcomes above.

Table 1
Clinical outcomes.

Construct	Measure	Assessment(s)
anxiety	Generalised Anxiety Disorder (GAD-7; Spitzer et al., 2006) (based on a 4-point Likert scale, 0=not at all, 3= nearly every day)	Baseline Post Intervention * 4-week follow-up * 8-week follow-up * 12-week follow-up †
depression	Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001) (based on a 4-point Likert scale, 0=not at all, 3= nearly every day)	Baseline Post Intervention * 4-week follow-up * 8-week follow-up * 12-week follow-up †
well-being	Warwick-Edinburgh Mental Well-Being Scale (WEMWBS; Tennant et al., 2007) (based on a 5-point Likert scale, 1=none of the time, 5= all of the time)	Baseline Post Intervention * 4-week follow-up * 8-week follow-up * 12-week follow-up †
resiliency	Brief Resilience Scale (BRS; Smith et al., 2008) (based on a 5-point Likert scale, 1= strongly disagree, 5= strongly agree)	Baseline Post Intervention * 4-week follow-up * 8-week follow-up * 12-week follow-up †
health status	EuroQol 5 Dimension 5 level (EQ-5D-5 L; EuroQol Research Foundation, 2019)	Baseline 12-week follow-up †
health and social care resource use	patient resource-use questionnaire/ health record review	Baseline 12-week follow-up †

* intervention arm only.
† 16-weeks post-baseline.

2.7. Analysis

2.7.1. Statistical analysis

Data will be analysed on a strictly Intention-To-Treat basis, with participant data analysed according to the arm to which they were randomly allocated. Protocol deviations will be noted and their frequency used to inform the power calculation for the larger study (c.f. contamination).

The following information will be presented in a CONSORT Diagram (or tabulated if easier and clearer, particularly if the data is to be presented by PCN):

- Number of participants with mild to moderate mental health difficulties identified.
- Number of ineligible participants (with reason(s) for ineligibility).
- Number of participants consented/ screened.
- Number of participants providing baseline data.
- Number of participants randomised, including by arm.
- Number of participants who received the treatment to which they were randomised including, if allocated to the intervention arm, the level of engagement with the intervention itself.
- Number of withdrawals from the intervention arm (with reasons).
- Number of withdrawals/ dropouts from the trial (with reasons) by trial arm (at all relevant time points).

Data on engagement with the intervention, by participants randomised to that arm, will be summarised using appropriate descriptive statistics, most likely frequency of session attendance and/ or the median/ modal number of sessions attended.

The following information will also be reported with 95 % C.I.'s. C. I's refers to the probability that a parameter will fall between a pair of values around the mean (this information will be for descriptive purposes only, with no formal comparisons between trial arms or any other sub-groups):

- The percentage of screened participants who are eligible for the study and, of these, the percentage who are subsequently consented and randomised.
- The percentage of randomised participants who complete the study (provide outcome data at post-intervention/ 4-weeks follow-up/ 8-weeks follow-up/ 12-weeks follow-up, where appropriate) by trial arm.
- In addition, the average monthly recruitment rate will also be determined. Graphs of current recruitment numbers (by month) and the numbers expected will be provided to the MEND Trial Steering Committee (TSC) and Trial Management Group (TMG) at regular intervals.

Participant socio-demographic data will be summarised, by trial arm, using appropriate summary statistics. For example, ethnicity, age and sex.

The number of participants providing clinical outcome data (for each measure) at all relevant time points (see Table 2) will also be reported, along with descriptive summaries of these outcomes. No model-based imputation (e.g. multiple imputation) of missing data items will be attempted - missing data items will assume the mean value of all completed items on that measure for a particular individual (assuming that sufficient items have been completed, as per Table 2). Questionnaire completion rates (i.e. the number of individual items completed), variability in the responses across participants and floor/ ceiling effects will also be reported.

In order to gauge the 'promise' of the prevention and promotion intervention, appropriate regression models will be fitted, using the 12-week post-intervention follow-up data as the outcome variable and age, gender, trial arm and the corresponding baseline data as covariates. The focus of these regression models will not be statistical significance, but

Table 2
Analysing clinical outcomes.

Measure	Number of Items	Number of Non-Missing Items Required to Calculate a Score	Calculation Method and Score Range	Appropriate Summary Method
GAD-7				
PHQ-9				
WEMWBS				
BRS				
EuroQol 5 Dimension 5 level				
Self-Report Questionnaire				

80 % C.I.'s for the trial arm coefficient.

2.7.2. Progression criteria

A traffic light system (Green = progress to definitive trial; Amber = modification needed; Red = do not progress) will be adopted to guide the decision to progress to a larger trial. Progression will be dependent on all criteria being either green and/ or amber. The following criteria have been chosen: (Table 3)

2.7.3. Health economic analysis

As a feasibility study, the comparative cost-effectiveness of the interventions will not be formally assessed. Instead, it will focus on the methods for the collection of data on resource use and health related quality of life (HRQoL), providing a basic descriptive statistical analysis. As part of the analysis, resource use data will be multiplied by the associated unit costs (NHS England & NHS Improvement, 2021); (Devlin et al., 2016) to determine total costs. National tariffs (Devlin et al., 2016) will be attached to the participants' health states resulting from the EQ-5D-5 L to estimate quality adjusted life years (QALYs). Descriptive statistics will be used to analyse participant's resource use and HRQoL. Resource use data will then be multiplied by the associated unit costs (NHS England & NHS Improvement, 2021) (Jones et al., 2023) to determine total costs. Participants' health states resulting from the EQ-5D-5 L will be converted into EQ-5D-3 L utility values for each time point following NICE guidance (National Institute for Health and Care Excellence (NICE), 2022), in order to estimate quality-adjusted life years (QALYs). Differences in total costs and QALYs will be analysed for each arm by the Health Economists using descriptive statistics.

2.7.4. Qualitative and process evaluation

Qualitative data will be collected to understand factors that facilitate or challenge the successful implementation of interventions (O'Cathain, 2018) and a process evaluation will be conducted to provide insight into the intervention's mechanisms of action (Medical Research Council, 2021).

- **Participants**: a patient experience questionnaire will be used to assess intervention acceptability. Semi-structured interviews will be conducted with a sample of participants (10 per arm), to explore their experience of the study and perceived mechanisms for change.
- **General practice staff:** A feedback questionnaire will be distributed to GP staff, to understand their experiences and any changes required for a full study. A semi-structured interview with three staff members will also be conducted.
- **Research team**: Field notes from the research team will identify factors that supported/impeded the feasibility study. A semi-structured interview will be conducted with the two Assistant Psychologists to understand their perceived mechanisms of change and patient safety processes.

Questionnaire responses will be collated, and interviews transcribed. Qualitative analysis will be conducted using NVivo, to provide a comprehensive response to the research questions. An inductive thematic analysis will be utilised to analyse data for recurrent themes. In addition, the process evaluation will allow for the identification of any mediating variables which should be measured in a full study.

Table 3
Outline of progression criteria.

Criterion	Green	Amber	Red
Participant Recruitment (% of $N = 60$ recruited in 6 months)	≥80 %	60 % - 80 %	<60 %
Acceptability - Intervention Engagement (attend all 4 sessions)	≥75 %	60 % - 75 %	<60 %
Participant Retention (at 12-weeks post-intervention)	≥80 %	60 % - 80 %	<60 %
Clinical Outcome Completion	≥80 %	60 % - 80 %	<60 %
Intervention Safety	minimal 'incidence' of 'support' and/ or few safeguarding incidents		

2.8. Adverse events

Minor and major adverse events (including Serious Adverse Events) will be monitored and recorded throughout the study. All Serious Adverse Events will be reported to the Trial Steering Committee. As per ethics committee requirements, Serious Adverse Events that are judged to be related to the intervention and unexpected will be reported to the NHS ethics committee immediately.

2.9. Dissemination

The research team will disseminate widely across all stakeholders (clinical, academic, service users, caregivers, Integrated Care Board (ICB) colleagues), ensuring accessibility in collaboration with the PPI committee throughout the project's lifetime. Specific outputs will include:

- Papers in high-impact academic journals
- Lay summaries on websites/social media and magazines
- Feedback to participants
- Dissemination events for academics, healthcare professionals and general audiences
- A full report for NIHR RfPB
- Submission for a larger trial, via HTA funding

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CRediT authorship contribution statement

Miranda Budd: Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Validation, Writing – original draft, Writing – review & editing, Data curation,

Formal analysis, Resources. **Kathryn Gardner:** Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Writing – original draft, Writing – review & editing, Supervision. **Gita Bhutani:** Conceptualization, Methodology, Supervision, Writing – review & editing, Funding acquisition, Data curation, Investigation, Writing – original draft. **Mark Hann:** Conceptualization, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing, Funding acquisition, Software. **Umesh Chauhan:** Conceptualization, Funding acquisition, Investigation, Methodology, Writing – original draft, Writing – review & editing, Supervision. **Sophie Jaber:** Investigation, Project administration, Writing – review & editing, Data curation. **Irem Shabir:** Data curation, Investigation, Project administration, Writing – review & editing. **Valerio Benedetto:** Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing. **Andrew Clegg:** Conceptualization, Formal analysis, Funding acquisition, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing. **Naim Ismail:** Conceptualization, Data curation, Project administration, Writing – original draft, Writing – review & editing. **Farah Lunat:** Conceptualization, Funding acquisition, Methodology, Project administration, Software, Supervision, Validation, Writing – original draft, Writing – review & editing.

Declaration of competing interest

The views expressed in this publication are those of the authors and not necessarily those of the funder (National Institute for Health and Care Research).

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