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

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ABSTRACT

Background: Mental health problems are typically addressed and intervened through a reactive approach rather than a proactive or preventative one. The aim of this feasibility RCT was to explore the possibility of recruiting to, and delivering a brief psychological intervention, focusing upon mental health prevention and promotion, in General Practice (GP).

Methods: This was a two-arm feasibility study where participants were randomised to either: treatment-as-usual (TAU) from their General Practitioner; or to a brief psychological intervention. Sixty-four participants, aged 16 and over, from 10 GP surgeries, with mild to moderate mental health difficulties, as measured by the PHQ9 and GAD7, were recruited. Intervention engagement data were summarised utilising descriptive statistics. Descriptive statistics were used to summarise clinical outcome measures at baseline and follow-up and to informally compare the two groups. Cost-effectiveness was investigated using descriptive statistics to analyse the resource use of participants and Health-Related Quality of Life (HRQoL). Qualitative data were analysed through thematic analysis and interpret in relation to Normalisation Process Theory, to understand implementation processes and the intervention's mechanism of change (facilitators and barriers).

Results: The recruitment target was met within the set timeframe. 230 patients were screened for eligibility, 72 of which were eligible and 64 were randomised. 80 % were female and 91.5 % identified as being white British. 19 dropped out, 9 of which were in the intervention arm and 10 from the TAU arm. The most frequent reason was reported as, no longer requiring support or being uncontactable. Clinical outcome measures were completed and demonstrated sensitivity to change. No participant safety factors were reported which would limit a larger trial and health economic data was collated. All of the progression criteria were classified as 'amber' meaning that progression to a definitive randomised controlled trial is warranted but modifications to improve recruitment, intervention engagement and participant retention is needed. Qualitative feedback was generally positive, with participants noticing therapeutic benefit, commenting on the ease of access and General Practitioners found the offer fitted well within GP.

Discussion: As a feasibility trial, the results demonstrate that individuals in GP can be recruited to a trial focusing upon the delivery of a brief psychological intervention and the required clinical assessments to assess effectiveness can be obtained. Qualitative feedback was positive from participants and GP staff and early indications seemed to demonstrate an improvement in wellbeing and a reduction in anxiety and depression. However, modifications for a larger trial are recommended to enhance recruitment and retention.

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1. Introduction

The prevalence of mental health problems and the number of people seeking help has been steadily rising in the United Kingdom (UK) (BMA, 2024). Depression and anxiety prevalence is projected to rise by 16 % from almost 1 in 6 in 2019 (6.7 million) to almost 1 in 5 in 2024 (9.1 million) (Watt et al., 2023). Often individuals initially contact their local GP, where they receive care and support or are guided into mental health services. 90 % of people with mental health problems are cared for entirely within primary care (Royal College of General Practitioners (RCGP, 2014) and around 30 % of people who see their General Practitioner have a mental health component to their illness (Jenkins et al., 2002). As both prevalence and demand rise, pressure will be felt by mental health services and GP.

The Mental Health Foundation has issued a stark warning that failing to prevent people from experiencing a deterioration in their mental health will lead to years of lives lost, and lives being damaged (Prevention Revolution, 2019). The cost of mental health problems to the National Health Service (NHS) is predicted to rise to unaffordable levels by 2026 if support arrangements do not change (Knapp & McDaid, 2011). In 2023, NHS England spent £217.5 million on medication to treat depression and anxiety (Mental Health Statistics UK, 2024) and over 8.6 million adults in England are now prescribed them annually (NHS Business Services Authority, 2023). Before Covid and the cost-of-living crisis, mental ill-health was the most common cause of sickness absence (Statista, 2021) with an estimated 17 million working days lost per year (Health & Safety Executive, 2022). In recent years, The Mental Health Foundation reported that poor mental health costs the UK £118 billion per year; £1.4 billion being costs to GP where much of it could be preventable (McDaid & Park, 2022).

With rising recognition of the importance to focus upon both preventative and promotional approaches in mental health care from numerous organisations (e.g., WHO, 2013, 2004; The King's Fund, 2016) and with studies and reviews showing that psychological preventative interventions are both clinically and cost-effective (e.g., Cuijpers et al., 2005; Cuijpers, 2009; Herrman & Jané-Llopis, 2005; Jane-Llopis et al., 2011; Stice et al., 2007; Van Zoonen et al., 2014; Knapp & McDaid, 2011; Gilbody et al., 2024), there is a need for a radical upgrade in preventative mental health practice. Although there are some promising results, there remains a lack of research in this area which may be impacting upon application into clinical practice (Budd et al., 2021). The Department of Health and Social Care (Department of Health & Social Care, 2017) states that there is a clear need for more research in mental health prevention and that funding programmes should encourage research at the phases during which mental health problems can be prevented.

In General practice, it seems the most common focus is upon subthreshold depression, exploring both the clinical and cost-effectiveness of a brief intervention when compared to usual care, with results demonstrating superior outcomes for the interventions measured (e.g., Fernández et al., 2018; Smit et al., 2006). Wong et al. (2021) aimed to assess the cost-utility and cost-effectiveness of a group-based behavioural activation with mindfulness vs usual care for treating subthreshold depression in primary care. Results demonstrated that the intervention was both cost-effective and helped prevent the development of major depressive disorder. There has been similar work focusing upon individuals ≥65 who screened positive for subthreshold depression in GP, across the North of England, which established both the clinical and cost-effectiveness of behavioural activation delivered over six sessions (Lewis et al., 2017).

General Practice has great potential to be a suitable place to engage in mental health prevention work; due both to the frequency with which the local community access the service and its non-stigmatising nature. The Royal College of General Practitioners made twelve recommendations for mental health promotion and prevention within UK GP (Thomas et al., 2016). Emphasis was placed on prevention as a strategy to help save lives, reduce illness, save money, reduce GP workload, promote resilience and positive mental health.

1.1. Research questions and objectives

This study aimed to understand the feasibility of delivering a brief psychological intervention, focusing upon mental health prevention and promotion, in NHS General Practice. To answer this, the following research questions led the study:

Question 1. Are participants who present in GP, with minimal-moderate mental health symptoms, as measured by the PHQ-9 and GAD-7, willing to be randomised into a study investigating a brief psychological intervention?

Objectives: Understand (1) the ability to recruit participants into the study and (2) the retention and attrition rates of participants within the study, including follow-up.

Question 2. What are the facilitators and barriers for acceptability and delivery of this psychological intervention in GP?

Objectives: To gather (1) participant (2) General Practitioner and (3) Assistant Psychologist (AP) feedback to optimise the intervention and full-scale study design.

Question 3. Is it feasible to collect the necessary outcome data to inform the clinical and cost-effectiveness of the psychological intervention for a future, larger trial?

Objectives: Understand the ability to collect (1) Clinical outcome data (participants' baseline and follow-up metrics) and (2) economic outcome data (participants' GP resource use).

Question 4. What participant safety factors need to be considered regarding the intervention procedures?

Objective: To understand if clinical and research staff can safely identify, share and manage risk-related information in GP.

2. Method

2.1. Design

This study was a two-arm feasibility study where participants were randomly allocated to either: treatment as usual (TAU); or treatment as usual in addition to a mental health prevention and promotion intervention (MEND).

2.2. Recruitment

Participants were recruited across two study sites: two Primary Care Networks (PCN; (Fisher et al., 2019)), totally 10 practices. Participants entered the study via three routes (self-referral, GP staff referral or GP database searches), as outlined in the CONSORT diagram (Fig. 1). A recruitment target of 60 participants, 30 per arm, was set, following recommendations that this is sufficient to assess feasibility outcomes with adequate precision to inform the sample size for a definitive study (Lancaster et al., 2002).

Following referral, or self-identification, the potential participant was then given further information about the study and informed consent was obtained. For those who consented, an eligibility check was then completed (see inclusion criteria) alongside baseline outcome measures. If consent was gained and the individual was eligible, the participant was then randomised. Half to receive TAU and half to the brief psychological intervention (MEND).

2.3. Inclusion / exclusion criteria

Individuals were included in the study if:

- Registered within GP in either PCN study site.
- Scored ≤14 on the GAD-7 and ≤15 on the PHQ-9 at eligibility screening

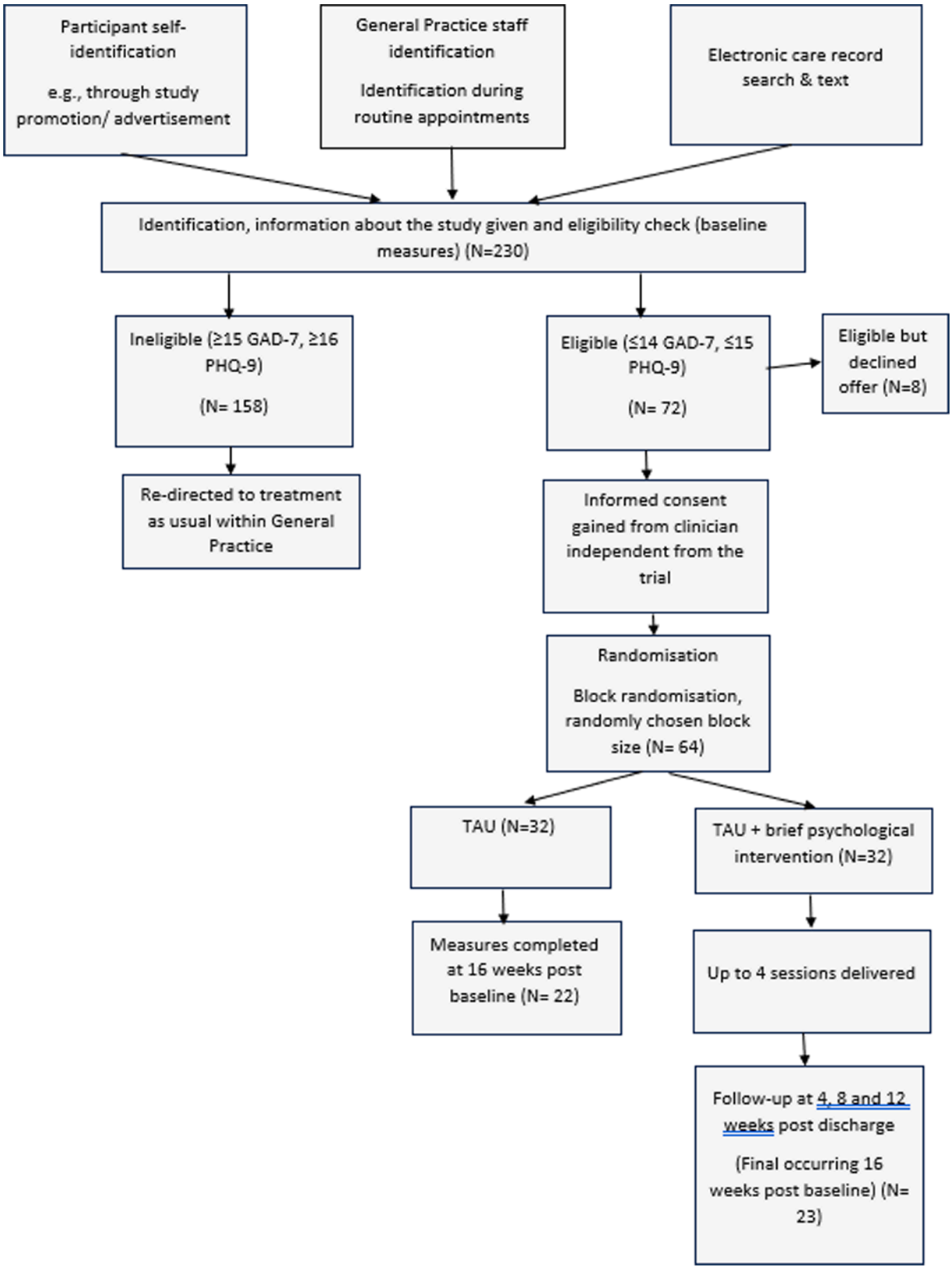

Fig. 1. Consort Diagram.

- Aged 16 or older.

Individuals were excluded from the study if:

- Already being supported by a mental health service / engaging in therapy elsewhere.
- A formal diagnosis of a severe mental health difficulty.

- A moderate to severe learning disability where the support provided could not meet their need(s).
- Requiring support from crisis services.

Non-English speakers were not excluded from the study due to the ability to use language line to interpret appointments if needed.

2.4. Randomisation

Randomisation occurred through the utilisation of a randomised block design (with random block sizes of 4 or 6; chosen at random), stratified by PCN. This was implemented via the online software programme *SealedEnvelope.com*. An individual, independent of the research team, informed the research team of the participants' allocation and the study's statistician was masked to arm allocation.

2.5. Interventions

2.5.1. Treatment as usual (TAU)

Participants randomised into the TAU arm received mental health treatment as usual in GP. If participants within this group chose to seek support, GP staff provided any usual form of mental health support.

2.5.2. Prevention and promotion intervention (MEND)

As well as treatment as usual, participants allocated into the intervention arm also received the brief psychological intervention. This was up to four one-to-one appointments, delivered by a trained Assistant Psychologist (AP). The AP received two weeks of training in brief psychological assessment, formulation and intervention and then weekly supervision with a qualified psychological practitioner to ensure fidelity and guide session planning.

The intervention consisted of an initial assessment session, followed by a psychological formulation session. The third and fourth sessions then focussed on guided self-help and teaching coping strategies that participants could utilise to manage and maintain their wellbeing. Referred to as the intervention sessions, the content was underpinned by various therapeutic modalities, for example, cognitive behaviour theory, motivational interviewing, solution focused approaches and dialectical behaviour theory. Appointments lasted up to 45-min and were delivered weekly, either face-to-face, virtually or via telephone dependent upon participant preference. The intervention structure was designed in keeping with the Template for Intervention Description and Replication (BMJ, 2014).

2.6. Data collection

The primary data collected were:

- Recruitment rates per month (referred, consented and randomised) and attrition rates.
- Intervention engagement (e.g. session attendance) and participant, GP staff and Assistant Psychologist (AP) acceptability.
- Clinical assessments completeness (questionnaires and health-resource use).
- Frequency of patient risk and safeguarding incidents reported.

The clinical assessment questionnaires completed were as follows: PHQ-9 (Spitzer et al., 1999), a measure of depression; GAD-7 (Spitzer et al., 2006), a measure of anxiety; Warwick and Edinburgh Wellbeing Scale [WEMWBS] (Tennant et al., 2007), a measure of wellbeing; Brief Resilience Scale [BRS] (Smith et al., 2008), a measure of resilience. These measures were completed at baseline and then 16-weeks later.

For both the PHQ-9 and GAD-7, higher scores are associated with more severity of symptoms and lower score with less severe. The BRS consists of six statements and you assign a score between 1 and 5 to each statement. The scores are added and divided by the number of statements to determine overall score. A higher score is associated with a higher level of resiliency. The WEMWBS is scored by summing the scores for each item (1–5 range). Total scores range from 14 to 70, with a higher figure indicating greater positive mental wellbeing. Health resource use and health-related quality of life (HRQoL) were measured at baseline and final follow-up.

2.7. Data analysis

2.7.1. Statistical analysis

Data were analysed according to the arm to which the participant was randomly allocated (intention-to-treat). Any protocol deviations were noted.

The primary focus of this study was on logistic-type outcomes, that is, outcomes that are not directly of a clinical type (e.g., related to recruitment, retention, intervention acceptability etc.). The number of potential participants screened, subsequent eligibility for the study and subsequently consented and randomised (by arm), are presented in a CONSORT diagram (Fig. 1). Attrition rates were calculated and presented with 95 % confidence intervals, along with reasons for dropping out. For those allocated to the intervention arm, treatment engagement was summarised using frequencies/ percentages.

Socio-demographic characteristics and clinical questionnaire completion rates and total scores were summarised using appropriate descriptive statistics.

2.7.2. Health economic analysis

A preliminary health economic analysis from a healthcare system and participants' perspective was conducted. This included data on resource use and health-related quality of life at baseline and follow-up. For resource use, research staff filled in a pre-specified questionnaire adapted from previous evaluations (Schweikert et al., 2008; Thompson, 2001; Hives et al., 2023). It covers different types of professionals and resources that participants might have used during the previous 6 months (at baseline) or 16 weeks (at follow-up) to help with their mental health. Questions focused on:

(i) Private appointments and stays in private hospital or clinics;
(ii) Medicines and health supplements bought without prescription;
(iii) Equipment;
(iv) NHS appointments, referrals and activities;
(v) Admissions to Accident and Emergency, hospital or rehabilitation clinic;
(vi) Prescribed medicines;
(vii) Changes to medicines already prescribed at baseline (asked at follow-up only).

Given it was a feasibility study and the uncertainty around specific health and social care services received by the participants during the study period, a formal cost analysis was not undertaken.

Health-related quality of life data were collected using the EuroQol-5 Dimensions-5 Levels (EQ-5D-5 L). Participants' health states resulting from the EQ-5D-5 L were converted into EQ-5D-3 L utility values (Hernández-Alava & Pudney, 2018) following relevant guidance, to estimate quality-adjusted life years (QALYs). Descriptive analysis was performed using Stata 17 (StataCorp, 2021). Although results are presented for both arms, comparisons should be interpreted cautiously given the exploratory nature of the analysis.

2.7.3. Qualitative analysis and process evaluation

The study embedded a qualitative process evaluation (Medical Research Council, 2021) to understand facilitators and barriers to the successful implementation of the intervention (O'Cathain, 2018). Data were collected via individual questionnaires or field notes along with individual semi-structured interviews. Analysis was conducted utilising NVivo and interviews were coded and transcribed by the sixth, seventh

and tenth authors who were all research assistants, supervised and guided by the third author who is an experienced qualitative researcher. Normalisation Process Theory (NPT; May et al., 2009) was utilised as a conceptual framework to shape some of the interview questions in the topic guide. Transcripts and questionnaire responses were analysed using inductive thematic analysis (Braun & Clarke, 2020), allowing for recurring themes within the data to be identified, debated and agreed by the team, within and across multiple stakeholders:

1. Participants: a participant experience questionnaire was used to assess the acceptability of the intervention. Semi-structured interviews were conducted with 12 participants (7 from the intervention arm and 5 from the TAU arm).
2. GP staff: A feedback questionnaire was distributed to GP staff to understand their experiences and any changes they felt were required for a larger trial. Semi-structured interviews were conducted with three staff members; one General Practitioner, one Social Prescriber and one Mental Health Practitioner (MHP).
3. Research team: Field notes completed by the research team identified factors that facilitated/hindered the feasibility study. Semi-structured interviews were also conducted with the two Assistant Psychologists (AP).

The resulting inductively derived themes are then discussed in relation to processes/factors that facilitate or hinder the study, using the four areas of NPT to organise the findings. NPT is concerned with the social organisation of the work (implementation) of making practices routine elements of everyday life (embedding) and of sustaining embedded practices in their social contexts (integration). NPT aims to explain the routine embedding of practices by reference to the role of four generative mechanisms: coherence; cognitive participation; collective action and reflexive monitoring.

2.8. Ethics

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

3. Results

64 participants (13 males, 51 females) were recruited from GP across two PCNs in Lancashire, UK.

3.1. Trial logistics

3.1.1. Recruitment rates and intervention engagement

230 potential participants were screened for eligibility during a 6-month recruitment window, of whom 72 were eligible. Of these, 64 were randomised [27.8 % of 239: 95 % C.I. (22.1 %, 34.1 %)]. Thirty-two patients were allocated to each trial arm, although only thirty were offered the intervention (the other two patients received TAU in error).

Table 1 illustrates the socio-demographic characteristics of participants recruited to the study. Characteristics are reasonably well-balanced between the two arms. The vast majority were aged between 26 and 65 (81.4 %), were female (80.0 %) and of white ethnic origin (91.5 %). The most common reason for visiting the practice related to concerns about worry and anxiety; 61.0 % of participants had previously accessed mental health services.

By 12-weeks post-intervention, 22 participants had dropped out the study [34.4 %: 95 % C.I. (22.9 %, 47.3 %)], ten who were randomised to receive the intervention and 12 TAU.

The above information is presented in a CONSORT diagram (see Fig. 1). In relation to attrition rates, 19 / 64 dropped out (30 % - 9 from intervention and 10 from TAU) – 45 / 64 completed data collection (70 %). Various reasons were given by participants. In the intervention arm, two reported no longer needing support, two had an appointment with NHS Talking Therapies and five became uncontactable either before starting or mid-way through. In the TAU arm, two reported they were disappointed with being allocated to TAU, two reported they did not require a follow-up, one was receiving counselling at the time of follow-up so declined and five were uncontactable before or after booking in a follow-up appointment.

Table 1
Socio-demographic and health information.

	MEND	TAU
Randomised	32	32
Provided Baseline Data	31	28
Age-Group (years)		
≤ 25	3 (9.7 %)	4 (14.3 %)
26–45	12 (38.7 %)	12 (42.9 %)
46–65	14 (45.2 %)	10 (35.7 %)
> 65	2 (6.5 %)	2 (7.1 %)
Sex *		
Female	25 (80.6 %)	23 (79.3 %)
Male	6 (19.4 %)	6 (20.7 %)
Ethnic Origin		
White (British/ Other)	27 (87.1 %)	27 (96.4 %)
Pakistani	4 (12.9 %)	1 (3.6 %)
Marital Status		
Married/ Partnered	22 (71.0 %)	20 (71.4 %)
Single/ Widowed/ Divorced	9 (29.0 %)	8 (28.6 %)
Education ^		
Secondary	10 (32.3 %)	6 (22.2 %)
College/ 6th Form	7 (22.6 %)	15 (55.6 %)
University	14 (45.2 %)	6 (22.2 %)
Employment		
Employed (FT or PT)	19 (61.3 %)	15 (53.6 %)
Unemployed	6 (19.4 %)	8 (28.6 %)
Economically Inactive $	6 (19.4 %)	5 (17.9 %)
Mental Health History		
Anxiety alone	7 (22.6 %)	6 (21.4 %)
Depression alone	3 (9.7 %)	2 (7.1 %)
Anxiety + Depression	12 (38.7 %)	14 (50.0 %)
PTSD	1 (3.2 %)	1 (3.6 %)
No Previous History	8 (25.8 %)	5 (17.9 %)
Previous access to MH services		
Yes	17 (54.8 %)	19 (67.9 %)
No	14 (45.2 %)	9 (32.1 %)
Reason for Consultation # (multiple reasons permitted)		
General Well-Being	5	1
Grief/ Loss	1	0
Low Mood	18	19
Physical Health	5	0
Stress	5	2
Worry/ Anxiety	22	18
Other Reason	1	0

* $N = 29$ for TAU group.
^ $N = 27$ for TAU group (1 x 'prefer not to say').
$ Retired + Student.
# based on $N = 32$ in both groups Of the 32 participants allocated to receive the intervention, 21 completed all 4 sessions (65.6 %), five completed 1–3 sessions and four did not complete any sessions. The other two participants were not offered the intervention in error.

3.2. Qualitative analysis with embedded process evaluation

3.2.1. Participant, GP staff and assistant psychologist acceptability

Participants, GP staff and Assistant Psychologists from the research team were interviewed as part of understanding the feasibility of the study. The themes and subthemes derived from the thematic analysis are listed in Table 2.

Given the volume of data, the supporting narrative focuses on the superordinate themes only across the three participant groups. To aid interpretation, the themes have then been mapped onto the four areas of NPT across the three participant groups.

Table 2
List of Participant, GP staff and Assistant Psychologist (AP) themes and subthemes and mapping to NPT constructs.

Participant Themes	
Superordinate Themes	Subthemes
Therapeutic benefit Reflexive monitoring	Understanding the self Understanding others Validation and reassurance Safe space to talk
Practitioner qualities Cognitive participation	–
Access to intervention[1] Cognitive participation	Importance of early intervention and meeting demand Stepping stone and onward referrals Lack of awareness of available services
Previous experience of support Coherence	–
Time restriction Collective action	The benefits of little time More time is needed
Study processes[1] Collective action	–
Clinic environment Collective action	–
GP Staff Themes	
Superordinate Themes	**Subthemes**
Study processes[1] Collective action	–
Staff workload Collective action	It makes all jobs easier
Access to intervention[1] Cognitive participation	Increased support available for patients Immediate support
Educational benefits Reflexive monitoring	–
Suggestions for next steps Reflexive monitoring	–
Assistant Psychologist Themes	
Superordinate Themes	**Subordinate Themes**
Finding their feet Cognitive participation	Settling in Building connections
Study promotion Collective action	–
Learning through trial and error Collective action	–
Appropriate and suitable intervention Reflexive monitoring	–
Personal development Reflexive monitoring	–
Therapeutic facilitators Cognitive participation	–

[1] Overlapping themes

Notes: Coherence (making sense of the purpose of the intervention, individually or with others, and its possibilities compared with existing practice).

Cognitive participation (cognitive 'buy-in' (e.g., is it a good idea?) and the relational work that people do to support the engagement required to implement the intervention).

Collection action (operational work, resources and the actions taken to implement the intervention within the practices).

Reflexive monitoring (reflections, appraisal, and feedback in relation to the impact (costs and benefits) of the intervention.

3.2.2. Coherence

Participants made sense of the intervention by referring to previous experiences of support, thereby bringing their hopes and expectations (one of the common factors in psychological work that contributes to good outcomes, (Duncan, 2014) to the intervention.

> *"I was comfortable with it. Because I'd obviously done that therapy before." (Participant, intervention arm)*

3.2.3. Cognitive participation

Participants described the importance of the practitioner's interpersonal qualities in facilitating engagement.

> *"Yeah, it did benefit me. It helped that you are so caring and you know, good at listening." (Participant, intervention arm)*

Both participants and General Practitioners appeared to 'buy-in' to the intervention because it provided access to preventative mental health intervention, where none has been available.

> *"There's a good preventative offer for physical health conditions and that same offer for mental health conditions hasn't been there. So the more that can be there, the better." (GP)*

The APs reflected on the importance of finding their feet by settling into the role and building professional relationships.

3.2.4. Collective action

Participants highlighted time as either a facilitator or barrier to change, depending on whether a brief intervention was deemed sufficient or insufficient, respectively.

> *"Because it's short the intervention, I think it really helps you to be active in doing something about it… so you've got to focus because you've only got so many sessions" (Participant, intervention arm)*

An informal and familiar environment was also appreciated by some; and both participants and GP staff commented on operational study processes, such as being organised and well-integrated, with APs as a point of contact about the intervention.

> *"We've got all the different roles within the PCN now. And I think it's a really good one to sort of slot in there as well." (Social Prescriber)*

Staff initially described an increase in workload, as they had to learn about the study, but this then lead to a decrease in workload, whilst APs reflected that being visible in the service and a 'trial and error' approach were essential to promoting the study and receiving referrals.

> *"In the long run, it makes all our jobs easier….so beneficial for the patient and the practitioner." (Social Prescriber)*

> *"I underestimated how much contact would actually be needed to get [referrals]…I think the biggest thing that made the difference towards the end of recruitment was a lot more face to face contact" (AP).*

Interviews and field guides from APs demonstrate how the project developed through trial and error in recruitment and methodology.

Some of these challenges related to room availability and space. Recruitment was enhanced through the use of Electronic Care Record (ECR) searches, although large numbers of people were inappropriate for the study. Referrals from social prescribers or GP staff were generally more appropriate:

> *"[Staff] knew what to look out for and they were aware of the criteria, so it wasn't a lot of going back and forth" (AP).*

3.2.5. Reflexive monitoring

Participants described therapeutic benefits due to the intervention, providing an opportunity to learn about themselves and giving them a reflective space for introspection. GP staff were keen to highlight the gap the intervention addressed and the need to offer this to more patients.

> *"People being aware that we're participating in a study that's helping people with their mental health, I think it always makes people a little bit more aware of that, of that topic. And can then improve it. Makes you ask questions about the service you provide." (GP)*

> *"I'd say possibly more surgeries… I think more patients should be offered something like this" (MHP)*

The therapeutic benefits were echoed by the APs, who also felt a

sense of personal and professional development through the training and supervision received.

3.3. Clinical assessments completeness

3.3.1. Clinical measures

Table 3 presents summary statistics for the four clinical questionnaires, to demonstrate completeness of data collation and sensitivity of data. None of the measures showed obvious signs of either floor or ceiling effects in either group at baseline, although the PHQ-9 was 'capped' at 15 and the GAD-7 at 14 due to the eligibility criteria. By 16-weeks post-baseline, there was evidence of floor effects in the intervention group for both these measures (but insufficient to indicate any analytical problems, e.g., excessive skewness).

For both the WEMWBS and the BRS, a higher score indicates a higher level of wellbeing and resilience, respectively and for the GAD-7 and PHQ-9, a lower score indicates a lower level of anxiety and depression, respectively.

In both study arms, the second and third columns are the most directly comparable as they are based on the same subset of participants at both time points. In the intervention arm (labelled MEND), the mean WEMWBS score increased by more than 7 points at 16 weeks post-baseline, demonstrating improved well-being. The BRS score, representing resilience to recover from stress, increased only marginally. Both the PHQ-9 and GAD-7 scores had decreased by around 3.5 points by week 16, suggestive of improved symptoms of both anxiety and depression. In the TAU arm, none of the mean scores had improved greatly (if at all) by week 16. This only represents a descriptive summary of change within groups: the aim of the study was not to demonstrate between-group effectiveness due to being insufficiently powered.

3.3.2. Health resource use

The key results from the resource use analysis are presented in Table 4. Resource use data was collected for 100 % of the randomised participants at baseline and 96.88 % of participants at follow-up. At baseline, 28 MEND participants (87.50 %) and 25 TAU participants (78.13 %) had visited at least 1 NHS healthcare professional during the previous 6 months. At follow-up, 14 MEND participants (45.16 %) and 18 TAU participants (58.06 %) visited at least 1 NHS healthcare professional during the previous 16 weeks. Most participants had appointments with a GP (100 % of participants at baseline, and just over three-quarters for participants at follow-up). A small number of participants ($n < 5$ in each arm) had appointments with other types of healthcare professionals (e.g., mental health practitioners, social prescribers, NHS Talking Therapies).

At baseline, 18 MEND participants (56.25 %) and 16 TAU participants (50.00 %) had prescriptions for medicines for mental health in the previous 6 months, while 15 MEND participants (48.39 %) and 18 TAU participants (58.06 %) had prescriptions for medicines in the previous 16 weeks. Of these, the majority had 1 prescribed medicine. Changes to

Table 4
Healthcare resource use at Baseline and Follow-up – main results.

Timepoint	Baseline[a]		Follow-up[b]	
Study arm (valid sample size)	MEND (N = 32)	TAU (N = 32)	MEND (n = 31)	TAU (n = 31)
No. of participants who visited an NHS healthcare professional (%)	28 (87.50)	25 (78.13)	14 (45.16)	18 (58.06)
GP	28 (100.00)	25 (100.00)	11 (78.57)	14 (77.78)
Psychologist (through referral)	0 (0.00)	0 (0.00)	4 (28.57)	9 (50.00)
MHP	2 (7.14)	0 (0.0)	2 (14.29)	2 (11.11)
Social prescriber	2 (7.14)	3 (12.00)	3 (21.43)	1 (5.56)
111 call	0 (0.00)	1 (4.00)	0 (0.00)	0 (0.00)
NHS Talking Therapies	2 (7.14)	1 (4.00)	2 (14.29)	0 (0.00)
Health and wellbeing coach	0 (0.00)	0 (0.00)	1 (7.14)	0 (0.00)
No. of participants who were prescribed medicines (%)	18 (56.25)	16 (50.00)	15 (48.39)	18 (58.06)
1 medicine	14 (77.78)	13 (81.25)	14 (93.33)	17 (94.44)
2 medicines	4 (22.22)	3 (18.75)	1 (6.67)	1 (5.56)
No. of participants who had a change in medicines already taken at beginning of study (%)	NA	NA	8 (25.81)	5 (16.67)
Course ended[c]	NA	NA	8	4
Increased dosage[c]	NA	NA	2	1

GP: general practitioner. MHP: mental health practitioner. NA: not applicable.
[a] Questions at Baseline applied to resources used in the previous 6 months.
[b] Questions at Follow-up applied to resource used in the previous 16 weeks.
[c] Sum of 'Course ended' and 'Increased dosage' is not equal to the total number of people who had a change in prescribed medicines, as some people had more than 1 change.

Table 3
Descriptive summaries, completeness and sensitivity of clinical data collated.

	MEND			TAU		
Measure	Baseline (All)	Baseline (if still in study at week 16*)	Week 16	Baseline (All)	Baseline (if still in study at week 16)	Week 16
WEMWBS						
N	29	22	22	29	20	20
Mean (SD)	***36.9 (10.2)***	***36.8 (9.1)***	***44.1 (10.2)***	***36.5 (6.6)***	***36.1 (6.5)***	***37.7 (9.3)***
Median (IQR)	35 (31, 44)	35 (31, 44)	41.5 (38, 53)	38 (32, 41)	37 (31, 41)	38(32,42.5)
Range	19–62	19–60	23–65	22–47	22–47	23–61
BRS						
N	29	22	22	29	20	20
Mean (SD)	***17.1 (4.4)***	***17.8 (3.9)***	***19.1 (4.8)***	***15.3 (3.7)***	***15.3 (3.9)***	***14.8 (3.7)***
Median (IQR)	17 (14, 20)	17.5 (16, 21)	19.5 (15, 22)	15 (12, 18)	14.5(12,18)	15.5(12,18)
Range	7–24	9–24	12–30	9–24	9–24	7–21
PHQ-9						
N	31	22	22	31	20	20
Mean (SD)	***10.1 (3.6)***	***10.3 (3.5)***	***6.9 (5.8)***	***10.7 (3.6)***	***11.2 (2.7)***	***11.6 (6.2)***
Median (IQR)	9 (8, 14)	9 (8, 14)	5 (3, 10)	12 (9, 14)	11.5(10,12.5)	12 (7, 14.5)
Range	4–15	4–15	0–22	2–15	5–15	2–25
GAD-7						
N	31	22	22	31	20	20
Mean (SD)	***9.6 (3.8)***	***9.5 (3.6)***	***6.0 (5.1)***	***10.4 (3.2)***	***11.3 (2.3)***	***11.8 (4.6)***
Median (IQR)	10 (6, 13)	9.5 (6, 13)	4 (2, 10)	11 (9, 13)	12 (10, 13)	12.5 (8,4.5)
Range	0–14	3–14	0–15	0–14	6–14	2–20

* 16 weeks post-baseline (12 weeks post-intervention end for participants in the MEND group).

medicines already prescribed at baseline occurred for 13 participants as recorded at follow-up (8 for the MEND arm and 5 for the TAU arm), with most changes involving the medicine's course being ended.

A small number of participants had appointments with private professionals at baseline. No participant bought over-the-counter medicines or equipment nor had admissions to A&E, hospital or rehabilitation clinic at baseline or follow-up.

Health-related quality of life data were collected using the EQ-5D-5 L for 90.63 % of participants at baseline and for 100 % of those who completed the follow-up. For those who had completed follow-up, at baseline the mean utility score attached to the MEND participants' EQ-5D-5 L health states was 0.65 (95 % CI: 0.53 to 0.77) and was 0.61 for the TAU participants (95 % CI: 0.48 to 0.73).

At follow-up the mean utilities scores were 0.67 (95 % CI: 0.54 to 0.79) and 0.62 (95 % CI: 0.46 to 0.77) for the MEND and TAU arms, respectively. The mean utility score changes were equal to 0.02 (95 % CI: −0.07 to 0.10) and 0.01 (95 % CI: −0.08 to 0.10) for the MEND and TAU arms, respectively. The resulting mean QALYs from baseline to follow-up were 0.20 for the MEND arm (95 % CI: 0.17 to 0.24) and 0.19 for the TAU arm (95 % CI: 0.15 to 0.23), as reported in Table 5.

3.4. Participant safety factors

During all interactions with the participants in the study, there were four documented examples of care initiated as a result of presenting risk or safeguarding concerns. One concern was related to potential risk to others and one to risk of domestic violence. In both cases, within UK GP everyday there is a 'Duty Doctor' on-call who was able to support and guide the Assistant Psychologist to ensure safe practice. Both cases related to potential safeguarding concerns, and for each, both the safeguarding lead in the practice and safeguarding team within the secondary care mental health provider organisation were consulted, with no further actions required.

Table 5
Participants' utility score - as estimated by converting responses to EuroQol 5-Dimension 5-Level (EQ-5D-5 L) questionnaire to EQ-5D-3-Level (EQ-5D-3 L) - at Baseline, Follow-up and change from Baseline to Follow-up and associated quality-adjusted life years, for those with follow-up data.

3-level utility score (based on 5-level health states) and QALYs for those with follow-up data ($n = 42$)		
Study arm	MEND	TAU
3-level utility score at Baseline		
Missing n (%)	0 (0.00)	0 (0.00)
Valid sample size n (%)	22 (100.00)	20 (100.00)
Mean	0.65	0.61
Standard deviation	0.27	0.27
95 % Confidence interval	0.53 to 0.77	0.48 to 0.73
Range	−0.13 to 0.89	−0.14 to 0.89
3-level utility score at Follow-up		
Missing n (%)	0 (0.00)	0 (0.00)
Valid sample size n (%)	22 (100.00)	20 (100.00)
Mean	0.67	0.62
Standard deviation	0.28	0.33
95 % Confidence interval	0.54 to 0.79	0.46 to 0.77
Range	0.05 to 0.99	−0.39 to 0.89
Change in 3-level utility score from Baseline to Follow-up		
Missing n (%)	0 (0.00)	0 (0.00)
Valid sample size n (%)	22 (100.00)	20 (100.00)
Mean	0.02	0.01
Standard deviation	0.20	0.19
95 % Confidence interval	−0.07 to 0.10	−0.08 to 0.10
Range	−0.63 to 0.36	−0.31 to 0.48
QALYs from Baseline to Follow-up		
Missing n (%)	0 (0.00)	0 (0.00)
Valid sample size n (%)	22 (100.00)	20 (100.00)
Mean	0.20	0.19
Standard deviation	0.08	0.09
95 % Confidence interval	0.17 to 0.24	0.15 to 0.23
Range	−0.01 to 0.29	−0.08 to 0.27

QALY: quality-adjusted life year.

3.5. Progression criteria

All of our progression criteria were classified as 'amber', meaning that progression to a definitive randomised controlled trial is warranted, but that 'modifications' are required to improve recruitment, intervention engagement and participant retention. This may be done through using staff already embedded within the surgery to deliver the intervention, as opposed to new team members who are not integrated. Provision of incentives for individuals to attend follow-up appointments could enhance retention.

4. Discussion

4.1. Summary

This study demonstrated that it is feasible to deliver a brief psychological intervention, focusing upon mental health prevention and promotion, in General Practice.

The first aim centred around feasibility to recruit and attrition rates, with results demonstrating that 230 participants were willing to be screened for eligibility, of which, 72 met the inclusion criteria and 64 were randomised. 19 out of the 64 participants dropped out, 9 of which were in the intervention arm and 10 in the TAU arm.

Logistical outcomes suggest that text messages sent out to patients, following searches conducted on the ECR increased levels of interest in the study, but many were not appropriate, i.e., scored within the 'severe' range on either the PHQ-9 or GAD-7, so were excluded. This may be because people are more motivated to act when they perceive a more significant problem (Tunks et al., 2023; Salaheddin & Mason, 2016). Referrals through General Practice staff tended to be more appropriate, perhaps because there had been an interaction with a clinician ahead of the referral.

In relation to demographics, more females accessed the intervention than men. This difference is frequently seen in mental health services (Lubian et al., 2016). Most participants were white British. It is commonly the case that white British people represent the highest percentage out of all ethnic groups seeking mental health support (Gov.uk, 2017). However, both of these findings are somewhat problematic and future research should focus upon improving access rates of under-represented groups.

Through qualitative feedback, this study also aimed to understand the facilitators and barriers to delivery. Key facilitators included the value given to the interpersonal qualities and relationship built between participant and AP, acceptability of support location (i.e., local and familiar), the research and treatment offer being well-received by General Practice staff and being perceived as well suited to the current service offer. The additional learning gained by both General Practice staff and the AP staff was also cited as a facilitator. Barriers included estates challenges, perception about ongoing need and expressed discontent about being allocated to the TAU group from some participants. These factors are similar to previous research findings about barriers and facilitators (e.g., Tunks et al., 2023; Carroll et al., 2021).

This study explored the feasibility of collating outcome data that would be required for a larger trial exploring clinical and cost-effectiveness. Clinical measures were reliably completed and the improvements measured suggest the questionnaires are sensitive enough to capture change. Both the resource use questionnaire and the EQ-5D-5 L reached good levels of completeness at baseline and follow-up, demonstrating that their collection in a full trial could be feasible. The resource use data collection showed that participants visited a wider

range of healthcare professionals and undertook a wider range of activities than expected. Therefore, adjustments will be made to efficiently capture the healthcare resources at a full trial.

An essential part of this feasibility study was also to assess the number of risk-related or safety-related incidents. There were four documented examples of care initiated as a result of presenting risk or safeguarding concerns, all of which were dealt with within the structures already in place in General Practice, with no additional concerns or actions required.

4.2. Comparison with existing literature

The evidence base in relation to both the clinical and cost-effectiveness of mental health prevention work is growing (e.g., 15–22). Recent studies, focusing upon preventative interventions integrated into General Practice have shown promise (e.g., 25, 28), with the CASPER trial (Fernández et al., 2018) demonstrating benefits for older adults with subthreshold depression to be maintained as 12-month follow-up, reducing the proportion of people who went on to develop case-level depression.

It can take time to develop collaborative working relationships within General Practice (Baird & Beech, 2020), with a shared vision cited as being essential. The multi-disciplinary teams in General Practice are growing and there are opportunities to up-skill the growing workforce in preventative approaches, in line with recommendations to enhance the preventative mental health care offer (e.g., NHS England, 2016; Thomas et al., 2016; Mind, 2018).

4.3. Strengths and limitations

This feasibility study explored the possibility of delivering a RCT within GP to compare TAU with a brief psychologically-informed intervention to prevent mental health distress. Strengths include the successful recruitment of the required number of participants, having trained and embedded staff within GP and General Practice staff reporting how well the approach both embedded and benefits participants. Outcome data was collated and demonstrated enough sensitivity to capture change. Positive feedback was also provided by participants, particularly in relation to receiving personalised early help in a location convenient and suitable for them.

The study was a feasibility study, as opposed to an efficacy study, so results would benefit from a larger trial, where efficacy data can be explored. The drop-out rate was not insignificant, and participants reported discontent at being allocated to TAU. Retention rates for a larger trial may be improved with the offer of an incentive to return for follow-up appointments. Access rates for under-represented groups in both mental health care and mental health research needs additional attention in a larger trial to improve generalisability of findings. Research staff (APs) reported that it took time for them to embed within General Practice and a larger future trial may benefit from instead training existing General Practice staff (e.g., social prescribers, MHPs) in the approach, as opposed to recruiting new and additional team members.

4.4. Future implications

All of the progression criteria were classified as 'amber' meaning that progression to a definitive randomised controlled trial is warranted but with modifications to improve recruitment, intervention engagement and participation retention. For a larger trial, General Practice staff should be trained and supervised to deliver the intervention, as opposed to funding Assistant Psychologists to join the team, to align with national guidelines and make wider roll-out more feasible. It is hoped that established team members will have a positive impact upon the study's ability to recruit and retain, through knowing the processes and systems the practice operates by and the need for time to embed will not be a barrier.

In the UK, a recent change in Government has led the development of a '10-year plan for health and care', with a focus upon three future shifts. One being a shift 'from sickness to prevention' (Anon, 2024). It is therefore very timely to proceed to a larger efficacy trial. Whilst there is already research to suggest preventative mental health care is effective, the evidence base needs strengthening. This will facilitate the actualisation of preventative mental healthcare.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Dr Miranda Budd reports financial support was provided by NIHR National Institute of Health Research. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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