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Mental health prevention and promotion in general practice settings

Submission date
13/06/2023

Recruitment status
No longer recruiting

Registration date
05/07/2023

Overall study status
Completed

Last Edited
28/02/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The number of people struggling with their mental health is rising. Soon, the NHS may not be able to meet the demand on mental health services. Offering preventative mental health support may stop people from developing more serious mental health problems. The study aims to understand how preventative mental health support can be delivered in a general practice (GP) setting.

The study will recruit individuals from GP settings and randomly allocate them to two groups. One group will be invited to engage in a brief, menu-based psychological intervention alongside their treatment as usual. The main aim of the intervention is to explore if it's possible to help people when they are first struggling, by teaching them how to look after their emotional wellbeing. The second group will receive treatment as usual and the research team will stay in touch with them too.

The feasibility study will test:
1. Whether people are happy to sign-up for, and then stay in the study.
2. Whether people are happy to fill in questionnaires about their wellbeing.
3. What helped, or indeed, stopped the study from running smoothly.
4. Whether the study is safe for everyone involved.

We will look at how many people sign up, attend or drop out of the intervention to answer these questions. Questionnaires/interviews will be done with participants, GP staff and the assistant psychologists to understand why the intervention service worked/did not work and how they felt about the study design.

As a new area of research, this 'feasibility study' is needed to help design, plan and justify a larger study.

Who can participate?
60 adult patients at GP surgeries in East Lancashire, with mild-moderate mental health difficulties who agree to participate.

What does the study involve?
Half of the patients will receive the usual input from their GPs (10-minute appointments). The rest will be offered five weekly 45 minutes of the intervention session.

What are the possible benefits and risks of participating?
If you choose to participate in the study there is a possibility that you will be allocated to the group which does not receive the brief psychological intervention. On the other hand, if you are allocated to the group that receives the psychological intervention there may be times when you find talking about your mental health upsetting. For some people talking about their mental health can be hard however you will be supported by an appropriately trained professional.
The aim of the psychological intervention is to help you feel better and to help you understand how to care for your mental health, just like you do your physical health. Therefore, it is hoped that the benefits of receiving the intervention will be improved emotional wellbeing.

Where is the study run from?
Lancashire & South Cumbria NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2023 to June 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Farah Lunat, Farah.lunat@lscft.nhs.uk

Contact information

Type(s)
Principal Investigator

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Dr Miranda Budd

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
323448

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56061, NIHR204332, IRAS 323448

Study information

Scientific Title
Mental health prevention and promotion in general practice settings: a feasibility study

Acronym
MEND

Study objectives
Will patients registered at a general practice, presenting with mild-moderate mental health difficulties, be willing to be randomised to a study investigating the efficacy of a brief mental health prevention and promotion intervention?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/05/2023, Health Research Authority (Skipton House, 80 London Road, London, SE1 6LH, United Kingdom; +44 (0)20 7972 2545; hra.approval@nhs.net), ref: 23/NW/0117

Study design
Interventional mixed methods

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Primary care mental health

Interventions

Patients who meet the criteria and agree to participate in the study will be randomised to either:
- treatment as usual within general practice
- treatment as usual within general practice plus a mental health prevention and promotion intervention

The mental health prevention and promotion intervention can be delivered either face-to-face in the GP surgery or virtually by an Assistant Psychologist, who has undergone an initial intensive 2-week training in the delivery of brief interventions for prevention and promotion. The virtual delivery method would be via integrated software such as ACCURX or iplato, which are both currently used by the practices in the two PCNs. The training the Assistant Psychologists will receive 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 be provided with weekly individual clinical supervision by a Clinical Psychologist.

Control group:
To mimic mental health treatment as usual in general practice, participants in both study arms will be able to access GP appointments as normal. Within these appointments, GP staff will be able to provide any usual form of mental health treatment, such as advice or medication. This feasibility study will collate data about the care each participant receives.

Intervention group:
The intervention group will receive additional input through a brief psychological intervention aimed at preventing mental ill-health, or deterioration. 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, over 5 sessions

Follow up for 16 weeks.

Qualitative and Process Evaluation
Qualitative data will be collected to understand factors that facilitate or challenge the successful implementation of interventions and a process evaluation will be conducted to provide insight into the intervention's mechanisms of action.

Intervention Type

Behavioural

Primary outcome measure

1. Depression measured using PHQ-9
2. Anxiety measured using GAD-7
3. Mental wellbeing measured using WEMWBS
4. Resilience measured using BRS

Measured at:
INTERVENTION ARM - engagement session (consent), first session (if engagement session was longer than 2 weeks ago), fourth session, Post-intervention (4-weeks post-baseline), 4-week follow up (8-weeks post-baseline), 8-week follow up (12-weeks post-baseline), 12-week follow up (16-weeks post-baseline).
CONTROL ARM - engagement session (consent) and 16 weeks later.

Secondary outcome measures
Cost-effectiveness outcome measures at baseline and the final follow-up (16 weeks):
1. Patients' resource use captured using a questionnaire and patient note review. The information to be collected from the participants' electronic health records (EHR) will be: NHS Consultations and referrals; A&E admissions and stays in hospital; Prescribed medication. The EHR that will be accessed is known as EMIS- the EHR used within the GP practices in Pendle West and Burnley East PCN. The questionnaire will collate information about: Private consultations and stays; Over-the-counter medication use; Special items or equipment.
2. Patients' health-related quality of life (HRQoL) measured using EuroQoL-5 Dimensions-5 Levels (EQ-5D-5L; 34) questionnaire

Qualitative and Process Evaluation
Qualitative data will be collected to understand factors that facilitate or challenge the successful implementation of interventions and a process evaluation will be conducted to provide insight into the intervention's mechanisms of action.
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 by the qualitative lead, KG, using NVivo, to provide a comprehensive response to the research questions. Furthermore, the process evaluation will allow for the identification of any mediating variables which should be measured in a full study.

Overall study start date
01/03/2023

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Registered at the research site's General Practice
2. Score <=14 on the GAD-7 and <=15 on the PHQ-9 at screening
3. Aged 16 years and above

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
64

Key exclusion criteria
1. Already supported by a mental health service/ engaged in therapy
2. Score >=15 on the GAD-7 and/or >=16 on the PHQ-9 at screening
3. Have a formal diagnosis of a severe mental health difficulty, where it would not be possible to meet their needs with four sessions
4. Require support from crisis services
5. Have a moderate-severe learning disability, where their needs could only be met within a specialist service.

Date of first enrolment
01/07/2023

Date of final enrolment
09/02/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancashire & South Cumbria NHS Foundation Trust Hq
Sceptre Point
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/10/2025

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Study sponsor R&D department, research.office@lscft.nhs.uk. Data available will be Individual participant data that underlie the results reported in this article, after deidentification (text, tables,figures, and appendices). The data will be available following study close out ending 5 years following article publication. Data will be available to Researchers who provide a methodologically sound proposal in order to achieve aims identified in the proposal. Data will be accessible on a secure NHS server and access will be facilitated by the research office but without investigator support other than deposited metadata.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

HRA research summary	20/09/2023	No	No