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Pilot trial of an evidence-based low intensity psychosocial intervention delivered by lay therapists for asylum seekers and refugees

Submission date
10/05/2019

Recruitment status
Suspended

Registration date
10/09/2019

Overall study status
Completed

Last Edited
06/11/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Asylum seekers and refugees (AS&Rs) have a higher prevalence of mental health problems, including depression, anxiety and post-traumatic stress disorder (PTSD), and functional impairment compared to other migrant groups and local majority populations. Persistence of mental health problems after resettlement is related to poor socio-economic conditions, acculturation-related stressors, economic uncertainty and ethnic discrimination. Asylum seekers and refugees encounter extensive barriers to accessing health care and have substantial unmet mental health needs. Making psychological therapies more accessible for asylum seekers and refugees is a national research priority. Problem Management Plus (PM+) is a trans-diagnostic psychosocial intervention, designed to be delivered by lay therapists. Developed by the World Health Organisation as part of its Mental Health Gap Action Programme, PM+ has shown significant benefit in trials in low and middle income countries. However, to date there is no evidence of effectiveness or cost-effectiveness of interventions such as PM+ offered by lay therapists to asylum seekers and refugees in high-income countries such as the UK. This study is being conducted as part of an overarching research project and is designed to assess the feasibility of an evidence-based low-intensity psychosocial intervention (PM+) delivered by lay therapists for asylum seekers and refugees. The aim is to provide preliminary information on the potential effectiveness of group or individual PM+ versus standard care for AS&Rs in terms of anxiety and depressive symptoms after 13 weeks.

Who can participate?
Adult asylum seekers (including those refused leave to remain) and refugees in Liverpool City Region who are in contact with participating NGOs, primary care teams including out of hours services, and other community-based welfare agencies.

What does the study involve?
Participants who consent to take part are assessed for suitability by a researcher. They are then randomly allocated to receive five weekly sessions of either individual or group Problem Management Plus, delivered by lay therapists, or to usual care and peer support. They are interviewed again by a researcher 13 weeks and 26 weeks later.

What are the possible benefits and risks of participating?
Participants will help the research team to find out whether PM+ could be useful for other people in similar situations; they may also learn new skills to improve their management of practical and common mental health problems. There are few risks to taking part in this research. Being a part of the study may involve discussion of sensitive or upsetting material which relates to experiences of migration and resettlement. If participants do experience any discomfort or disadvantage from taking part in this study, a lay therapist or researcher will advise what additional help may be needed and where to find it.

Where is the study run from?
University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
November 2019 to June 2021 (updated 12/04/2021, previously: August 2020 (updated 28/11/2019, previously: September 2019 to August 2020))

Who is funding the study?
National Institute of Health Research, Public Health Programme (UK)

Who is the main contact?
Dr Ross White, ross.white@liverpool.ac.uk
(updated 12/04/2021, previously: Prof. Chris Dowrick, cfd@liverpool.ac.uk)

Study website
http://www.prosper-trial.org.uk

Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Sponsor Ref: UoL001348; Funder Ref: 17/44/42

Study information

Scientific Title
Pilot trial of an evidence-based low-intensity psychosocial intervention (Problem Management Plus) delivered by lay therapists for asylum seekers and refugees

Acronym
PROSPER

Study objectives
PROSPER Pilot is being conducted as part of an overarching feasibility study, the overall aim of which is to determine whether it is possible to conduct a randomised controlled trial in the UK of an evidence-based psychosocial intervention based on PM+, delivered by lay therapists for distressed and functionally impaired asylum seekers and refugees

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/07/2019, Liverpool Research Ethics Committee (Health Research Authority, 3rd Floor, Barlow House, HRA NRES Centre, Manchester, M1 3DZ, UK; Tel: +44 (0)207 104 8197), ref: 19/NW/0345

Study design
Single-centre three-arm non-blinded pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Mental health

Interventions
Participants will be randomised in the ratio 1:1:1 to one of three arms: Individual Problem Management Plus (PM+), Group Problem Management Plus (PM+) or no PM+ (control arm - participants will receive usual care/peer support from voluntary organisation). Participants will be randomised using a secure (24-hour) web-based randomisation program controlled centrally by the Liverpool Clinical Trial Centre (LCTC). A personal login username and password, provided by the LCTC, will be required to access the randomisation system. Designated research staff will be issued with their personal login and password upon completion of training in the use of the system.

The PM+ intervention consists of five weekly face-to-face sessions, delivered either one-to-one or in groups. The first session opens with psychoeducation, including information on common reactions to adversity, the rationale for PM+, goal setting, and brief motivational interviewing. Sessions one to four each introduce an intervention strategy: (i) Managing Stress (slow breathing exercise); (ii) Managing Problems (using problem-solving techniques); (iii) Get Going, Keep Doing (applying behavioural activation techniques); and (iv) Strengthening Social Support. These strategies are applied by participants during the intervention session to problems they are facing. Each strategy is reviewed in subsequent sessions, with the application of strategies between sessions encouraged to enhance learning through repetition. The final session involves a revision of learning, education on preventing relapse, and ends with a culturally appropriate closing ceremony.

Participants randomised to the control arm will not be offered any PM+ but will be able to access all usual care and peer support offered by the participating NGOs. To control for time and attention, participants randomised to the control arm will be invited to attend a local AS&R NGO of their choice. They are put in contact with other AS&Rs from similar backgrounds and encouraged to meet together with these others on a weekly basis for five weeks.

Follow up for all participants will be at 13 and 26 weeks.

Intervention Type
Other

Primary outcome measure
Severity of combined anxiety and depressive symptoms measured using Hospital Anxiety and Depression Scale (HADS) at 13 weeks post-baseline

Secondary outcome measures
1. Severity of combined anxiety and depressive symptoms measured using HADS.at 26 weeks post-baseline
2. Subjective wellbeing measured using WHO-5 at 13- and 26-weeks post-baseline
3. Functional impairment measured using WHODAS 2.0 at 13- and 26-weeks post-baseline
4. Progress on problems for which participant has sought help, measured using PSYCHLOPS at 13- and 26-weeks post-baseline
5. Post-traumatic stress disorder measured using PCL-5 at 13- and 26-weeks post-baseline
6. Depressive disorder measured using PHQ-9 at 13- and 26-weeks post-baseline
7. Service and support use measured using CSRI at 13- and 26-weeks post-baseline

Overall study start date
01/09/2018

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Asylum seekers and refugees
2. Age ≥18 years (self-reported)
3. Score of ≥8 on either the depression or anxiety subscale of HADS and score of ≥17 on WHODAS
4. Good working knowledge of one or more of English, Farsi, Urdu and Arabic
5. Registered with a GP in Liverpool City Region
6. Willing to provide relevant socioeconomic data (age, medical information etc)
7. Provided written informed consent

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
105

Total final enrolment
11

Key exclusion criteria
1. New arrivals to the UK (<28 days)
2. In Initial Accommodation and receiving Section 98 support for <28 days, due to high likelihood of dispersal outside the region
3. Imminent risk of suicide
4. Complex mental disorder (bipolar disorder/manic depression, or schizophrenia)
5. Cognitive impairment (moderate/severe intellectual disability, any dementia)
6. Substance misuse
7. Currently receiving a formal psychological therapy

Date of first enrolment
27/11/2019

Date of final enrolment
31/05/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Liverpool
Department of Health Services Research
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Government

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A dissemination group will be established, whose purpose will be to oversee the planned outputs from the PROSPER study. The researchers intend to publish the pilot trial protocol in 2019 and the pilot trial results in October 2020.

Intention to publish date
01/10/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/04/2020	30/04/2020	Yes	No
HRA research summary			26/07/2023	No	No
Results article		31/10/2022	06/11/2023	Yes	No