

Trials

Lay therapist delivered low intensity psychosocial intervention for refugees and asylum seekers (PROSPER): protocol for a pilot randomised controlled trial.

--Manuscript Draft--

Manuscript Number:	TRLS-D-20-00025R1	
Full Title:	Lay therapist delivered low intensity psychosocial intervention for refugees and asylum seekers (PROSPER): protocol for a pilot randomised controlled trial.	
Article Type:	Study protocol	
Funding Information:	Public Health Research Programme (17/44/42)	Professor Christopher Dowrick
Abstract:	<p>Background Asylum seekers and refugees (AS&Rs) experience impaired mental health and wellbeing, related to stresses in their country of origin, experiences in transit and reception on arrival, including significant barriers to accessing mainstream services. Their contact with healthcare is often crisis-driven and mediated through non-governmental organisations (NGOs).</p> <p>Problem Management Plus (PM+) is a psychosocial intervention recommended by the World Health Organization to address distress experienced by adults affected by humanitarian crises. We are investigating its application for the first time in a high income country.</p> <p>Methods In a pilot randomised controlled trial, PM+ will be delivered to AS&Rs in contact with NGOs in Liverpool City Region, UK, by lay therapists who have lived experience of forced migration. Following systematic review and stakeholder engagement, PM+ has been adapted to the local context, and lay therapists have been trained in its delivery.</p> <p>We will assess the feasibility of conducting a three-arm RCT of five 90-minute sessions of PM+, delivered individually or in groups by lay therapists to AS&Rs experiencing emotional distress and functional impairment, compared with each other and with usual support offered by local NGOs. Distress and impairment at baseline will be measured by Hospital Anxiety and Depression Scale (HADS) and WHO Disability Assessment Schedule (WHO-DAS). We aim to recruit 105 participants, 35 per arm.</p> <p>Primary health outcomes are anxiety and depressive symptoms at 3 months, measured by HADS. Secondary outcomes include subjective wellbeing, functional status, progress on identified problems, post-traumatic stress disorder, depressive disorder and service usage. Longer term impact will be assessed at 6-months post baseline, on the same parameters.</p> <p>We will assess the feasibility of conducting a full RCT in relation to the following elements: recruitment and retention of lay therapists and study participants; fidelity of delivery of PM+; and suitability of the study measures, including any linguistic or cultural barriers.</p> <p>Discussion We will use these findings to specify the parameters for a full randomised controlled trial to test the effectiveness and cost effectiveness of PM+ in reducing emotional distress and health inequalities, and improving functional ability and wellbeing, amongst asylum seekers and refugees.</p>	
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Response to Reviewers:	<p>Thank you for this positive review of our manuscript. We have interleaved responses below. We have also edited the author list on page 1 and related text on page 8, as one of our NGO colleagues has withdrawn from the study. We have now added change of authorship form plus email message from Alison Moore explaining why previous author Iqra Mahzir has withdrawn.</p> <p>-----Original Message----- From: em.trls.0.698dad.ae643688@editorialmanager.com <em.trls.0.698dad.ae643688@editorialmanager.com> On Behalf Of Trials (TRLS) Sent: 26 February 2020 10:59 To: Dowrick, Chris <cfid@liverpool.ac.uk> Subject: Your submission to Trials - TRLS-D-20-00025</p> <p>TRLS-D-20-00025 Lay therapist delivered low intensity psychosocial intervention for refugees and asylum seekers (PROSPER): protocol for a pilot randomised controlled trial. Rebecca Rawlinson; Rabeea'h Aslam; Girvan Burnside; Anna Chiumento; Malena Eriksson-Lee; Amy Humphreys; Naila Khan; Daniel Lawrence; Iqra Mahzir; Rachel McCluskey; Annette Mackinnon; Lois Orton; Atif Rahman; Ewan Roberts; Anna Rosala-Hallas; Rhiannon Tudor-Edwards; Philomene Uwamaliya; Ross White; Eira Winrow; Christopher Dowrick Trials</p> <p>[.....] Reviewer reports: Reviewer #1: This is the editorial comment</p>

This is a well written comprehensive protocol for a study for a pilot randomised controlled trial testing a lay therapist delivering low intensity psychosocial intervention for refugees and asylum seekers

SPIRIT checklist - It is not acceptable for Trials journal for the authors to leave any items blank, with N/A or miss out in the SPIRIT checklist. Further information giving rationale and why an item is not applicable is required. Please either edit the protocol and insert page numbers in the checklist or insert relevant information in the SPIRIT checklist.

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*Item 11b: Please state criteria for discontinuing or modifying allocated interventions for a given trial participant (e.g participant request, or improving/worsening condition.) Could state "There will be no special criteria for discontinuing or modifying allocated interventions".

This sentence is now added on page 13 and noted in Spirit checklist

*Item 11c: What were strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (e.g. drug tablet return, laboratory tests). Please edit protocol and insert page number in the SPIRIT checklist.

Text added p14 and noted in Spirit checklist

*Item 17b: N/A is not acceptable please write in the SPIRIT checklist (page 17) "the design is open label so unblinding will not occur".

Reference to existing text on page 17 now noted in Spirit checklist.

*Item 21b: I could not find information in the protocol on interim analyses and why there is not anticipated to be formal stopping rules for the trial. For instance, perhaps as this is a pilot study and there are no anticipated problems that are detrimental to the participant but please include and explanation in the protocol.

Existing text on page 19 now expanded and noted in Spirit checklist.

*Item 26b: Can suggest something like this "On the consent form, participants will be asked if they agree to use of their data should they choose to withdraw from the trial. Participants will also be asked for permission for the research team to share relevant data with people from the Universities taking part in the research or from regulatory authorities, where relevant. This trial does not involve collecting biological specimens for storage."

Text has been added to page 15, and this plus relevant text on page 22 now noted in Spirit checklist.

*Item 31b: page 26 you state the author contributions please insert page number into checklist or you could also state "All named authors adhere to the authorship guidelines of Trials. All authors have agreed to publication." Or All authors have contributed to writing the manuscript as detailed p26, no professional writers have been involved.

The indicated sentence has been added to the declaration on page 27, and noted in the Spirit checklist.

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Noted on page 15 of text that no biological specimens will be collected, and now also in Spirit Checklist.

*References: There were sixteen articles that could not be checked, please ensure information as in guidelines below. One article was not validated <https://trialsjournal.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol/#references>

Thank you, we have checked our reference list via PubMed and/or direct web links, and made the following amendments:

8.Slewa-Younan S, Uribe Guajardo MG, Heriseanu A, Hasan T. A systematic review of Post-traumatic Stress Disorder and depression amongst Iraqi refugees located in western countries. J Immigr Minor Health. 2015;17:1231-9.

10.van der Boor CF, White R. Barriers to accessing and negotiating mental health services in asylum seeking and refugee populations: the application of the candidacy framework. J Immigr Minor Health. 2020; 22:156-174. Review.

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41.National Institute for Health and Care Excellence. Methods for the development of NICE public health guidance. 3rd ed. London; 2012. <https://www.nice.org.uk/process/pmg4/resources/methods-for-the-development-of-nice-public-health-guidance-third-edition-pdf-2007967445701> [accessed 6 March 2020].

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45.McManus S, Bebbington P, Jenkins R, Brugha T. Mental Health and Wellbeing in England. Adult psychiatric morbidity survey 2014. Health and Social Care Information Centre, 2016. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/556596/apms-2014-full-rpt.pdf [accessed 6 March 2020].

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<p>Within your manuscript, have you also included details of your trial registration at the end of your abstract? <ul style="list-style-type:disc"> Name of the registry Trial registration number Date of registration URL of trial registry record

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<p>Does your study have ethical approval?</p>	<p>Yes, and I have included the relevant documentation as an additional file</p>
<p>Has your study received funding?</p>	<p>Yes, the funding is external and not industry funded, and I have included the relevant documentation as an additional file</p>
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<p>funding application? as follow-up to "Has your study received funding?"</p> <p>"</p>	
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Lay therapist delivered low intensity psychosocial intervention for refugees and asylum seekers (PROSPER): protocol for a pilot randomised controlled trial.

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Abstract

Background

Asylum seekers and refugees (AS&Rs) experience impaired mental health and wellbeing, related to stresses in their country of origin, experiences in transit and reception on arrival, including significant barriers to accessing mainstream services. Their contact with healthcare is often crisis-driven and mediated through non-governmental organisations (NGOs).

Problem Management Plus (PM+) is a psychosocial intervention recommended by the World Health Organization to address distress experienced by adults affected by humanitarian crises. We are investigating its application for the first time in a high income country.

Methods

In a pilot randomised controlled trial, PM+ will be delivered to AS&Rs in contact with NGOs in Liverpool City Region, UK, by lay therapists who have lived experience of forced migration. Following systematic review and stakeholder engagement, PM+ has been adapted to the local context, and lay therapists have been trained in its delivery.

We will assess the feasibility of conducting a three-arm RCT of five 90-minute sessions of PM+, delivered individually or in groups by lay therapists to AS&Rs experiencing emotional distress and functional impairment, compared with each other and with usual support offered by local NGOs. Distress and impairment at baseline will be measured by Hospital Anxiety and Depression Scale (HADS) and WHO Disability Assessment Schedule (WHO-DAS). We aim to recruit 105 participants, 35 per arm.

Primary health outcomes are anxiety and depressive symptoms at 3 months, measured by HADS. Secondary outcomes include subjective wellbeing, functional status, progress on identified problems, post-traumatic stress disorder, depressive disorder and service usage. Longer term impact will be assessed at 6-months post baseline, on the same parameters.

We will assess the feasibility of conducting a full RCT in relation to the following elements: recruitment and retention of lay therapists and study participants; fidelity of delivery of PM+; and suitability of the study measures, including any linguistic or cultural barriers.

Discussion

We will use these findings to specify the parameters for a full randomised controlled trial to test the effectiveness and cost effectiveness of PM+ in reducing

emotional distress and health inequalities, and improving functional ability and wellbeing, amongst asylum seekers and refugees.

Trial registration:

ISRCTN15214107

Date registered: 10/09/2019

Link: <https://www.isrctn.com/ISRCTN15214107>

Keywords

Asylum seekers, refugees, mental health, psychosocial intervention, problem management, lay therapists, high income country, pilot randomised controlled trial.

Background

Introduction

The United Nations Refugee Agency estimates that 71 million people throughout the world have been forced to flee their homes as the number of protracted conflicts has increased. This has created more than 26 million refugees worldwide, of whom an estimated 126,720 live in the UK¹. UK Home Office figures indicate there were 34,354 asylum applications in the UK (main applicants only) in the year ending September 2019. During that year the UK offered asylum, humanitarian protection, alternative forms of leave and resettlement, to 19,480 people; there were 35,043 cases pending initial decision, of which 57% were more than 6 months old². Many applications are initially refused as a result of a complex system that makes it difficult for asylum seekers and refugees (AS&Rs) to provide the evidence needed to meet the criteria for gaining asylum.

AS&Rs have higher prevalence of psychological morbidity, including depression, anxiety and post-traumatic stress disorder (PTSD), and functional impairment than other migrant groups and local majority populations³⁻⁵. Mental health problems are particularly prevalent amongst war refugees⁶, with rates of PTSD up to 10 times higher than in the general population^{7,8}. Persistence of mental health problems after arrival in a host country is related to poor socio-economic conditions, acculturation-related stressors, economic uncertainty and ethno-racial discrimination^{5,9}. As a result, AS&Rs encounter extensive barriers to accessing health care^{5,10} and have substantial unmet mental health needs¹¹. In the UK, the situation is especially problematic for asylum seekers without leave to remain who are at risk of destitution yet are required to pay for specialist health care^{12,13}.

Psychosocial interventions for AS&Rs resettled in high-income countries (HICs) may provide significant benefits, however there are few studies of good quality^{14,15}. Evidence for the applicability of psychological interventions by non-specialists in low and middle-income countries (LMICs) has increased significantly¹⁶⁻¹⁹. Many countries, including the UK, are seeking to improve health care delivery by extending the roles of health professionals²⁰, increasing workforce capacity and enhancing quality of care²¹. Innovations developed in LMICs, including task-sharing²² and the Common Elements Treatment Approach²³, have the potential to address current challenges for mental health care in HICs²⁴, notably the lack of human resources to deliver mental health services to those in need.

Problem Management Plus (PM+), is a manualised brief multi-component intervention²⁵, recommended by the World Health Organisation as part of its mhGAP guidelines (http://www.who.int/mental_health/mhgap/en/). It is specifically developed to be amenable to cultural and linguistic adaptation for the local context. Based on evidence-based problem solving and behavioural

1 techniques, the intervention is trans-diagnostic by which we mean it applies the
2 same intervention strategies across various common mental health problems
3 clients may be experiencing. Addressing multiple problems at one time through
4 shared emotional mechanisms is efficient, reducing the practical challenge of
5 making differential diagnoses and learning multiple treatment manuals for
6 different mental health diagnoses^{26,27}.
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9 *Rationale*

10 PM+ has shown significant benefit in trials in LMICs^{25,28,29}. However, to date there is
11 no evidence of feasibility, effectiveness or cost-effectiveness of interventions such
12 as PM+ offered by lay therapists to AS&Rs in HICs.
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17 The rationale for undertaking a pilot trial of PM+ for AS&Rs, rather than
18 proceeding to a full multi-centre trial, is that there are several areas of
19 uncertainty regarding trial viability. These include the feasibility of recruiting and
20 retaining AS&Rs as study participants, the fidelity of intervention delivery, and the
21 acceptability and utility of proposed study measures³⁰. There may also be
22 inequalities in mental health and wellbeing between AS&R groups, depending on
23 their age, gender, nationality, education, occupational status, length of stay,
24 access to resources and their current legal status in the UK which could inform the
25 design of a full trial. As North West England has the largest number of asylum
26 seekers in dispersal accommodation in England (9521 in September 2019) it is a
27 suitable setting for the pilot trial.
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34 *Preparatory work*

35 The PROSPER Pilot Trial (hereafter referred to as the PROSPER Pilot) builds on a
36 preparatory phase aimed at developing the research team's understanding of
37 relevant issues, engaging with stakeholders, adapting the intervention and training
38 the facilitators.
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43 We conducted a systematic review (PROSPERO 2018 CRD42018104453) of barriers
44 and facilitators to uptake of psychosocial interventions delivered by lay therapists
45 to improve mental health and wellbeing of asylum seekers and migrants. We also
46 undertook six focus groups with local service providers and potential service users,
47 and held two open meetings for stakeholders, to gather views about the mental
48 health needs of AS&Rs and the potential utility of PM+.
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53 As a result, we made the following contextual modifications to promote uptake
54 and relevance of the PROSPER Pilot:

- 55 • Focus on English, Arabic, Farsi and Urdu, identified as four most common
56 languages currently spoken by AS&Rs in Liverpool City Region.
- 57 • Decision to exclude new arrivals and those in temporary accommodation: on
58 grounds of a) high probability of dispersal and hence unavailability for
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1 intervention and/or follow-up; and b) low probability of being registered with a
2 GP and hence unable to access trial safeguarding procedures.

- 3 • Alteration to text of PM+ manuals to reflect life in western urban settings,
4 rather than south Asian rural settings: e.g. 'home' not 'hut', 'reading' not
5 'rearing poultry', 'visit job centre' not 'speak with village elder'.
6
- 7 • Adapting the group PM+ case studies to include men.
- 8 • Matching therapists and participants on basis of gender and language, but not
9 on basis of religion, politics or culture.
- 10
- 11 • Identification of accessible 'safe spaces' for research interviews and delivery of
12 PM+ sessions, including availability of child care.
- 13
- 14 • Reimbursement of travel expenses for lay therapists and participants.
- 15
- 16 • Supervision and support of lay therapists to include boundary issues between
17 therapy and involvement in participants' lives, since the shared lived-
18 experience of the asylum process takes this study beyond the boundaries that
19 have been apparent in other contexts.
20

21 *Training*

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24 Person Shaped Support (PSS) is a health and social care charity, responsible for
25 training in and delivery of the PROSPER intervention. PSS provides a wide array of
26 services, including Spinning World, a specialist psychological therapies service for
27 AS&Rs and others who have experienced human right abuses and traumatic events.
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31 Two wellbeing mentors were appointed by PSS in September 2018. The following
32 month they and their supervisor received five days of intensive training from two
33 PM+ Master Trainers (from Liverpool and Amsterdam). This focused on the delivery
34 of the PM+ intervention strategies in both individual and group modalities, and on
35 skills in training and supervising lay therapists. Subsequently the wellbeing mentors
36 completed practice cases to embed their skills, and receive regular monthly
37 supervision from one of the PM+ Master Trainers which will continue throughout
38 the study.
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44 Fifteen people with lived experience of the asylum process were offered training
45 lay therapists, after a recruitment procedure organised through PSS. Training
46 began in March 2019 and included education in mental disorders, basic helping
47 skills, delivery of intervention strategies and self-care. Lay therapists received a
48 total of eight days of training, and were trained to deliver either individual or
49 group PM+. This was followed by training cases and a competency assessment. Ten
50 lay therapists successfully completed training and were assessed as competent: six
51 in individual PM+ (two Farsi-speaking men, one Arabic-speaking man, and three
52 women whose languages are Urdu, Farsi and English) and four in group PM+ (one
53 Urdu-speaking man and three women, whose languages are Arabic, Turkish and
54 Thai).
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Methods

Aim and objectives

This pilot trial is part of the PROSPER feasibility study, the overall aim of which is to determine whether it is possible to conduct a randomised controlled trial in the UK of the evidence-based PM+ psychosocial intervention, delivered by lay therapists for distressed and functionally impaired asylum seekers and refugees.

The primary objective of the PROSPER Pilot is to provide preliminary information on the potential effectiveness of group or individual PM+ versus standard care for AS&Rs, assessed using severity of combined anxiety and depressive symptoms at 13 weeks post-baseline measured using the Hospital Anxiety and Depression Scale (HADS).

The secondary objectives are to provide preliminary information on the potential effectiveness and cost-effectiveness of group or individual PM+ versus standard care for AS&Rs with regards to:

- Severity of combined anxiety and depressive symptoms at 26 weeks;
- Subjective wellbeing;
- Functional impairment;
- Progress on problems for which an individual has sought help;
- Post-traumatic stress disorder;
- Depressive disorder; and
- Use of services and supports from NHS, social care and voluntary organisations.

Design and setting

PROSPER Pilot is designed as a three-arm pilot study, with the features of a proposed future definitive randomised controlled trial. Participants will be randomised to receive individual PM+, group PM+ or the control (no PM+), in a ratio of 1:1:1.

The pilot trial is being conducted in Liverpool City Region. It utilises collaborative working between three universities (University of Liverpool, Liverpool John Moores University and Bangor University) and ~~three~~four NGOs offering advice and support to AS&Rs: PSS, ~~and~~ Asylum Link ~~and~~ , ~~British Red Cross~~ ~~and~~ ~~Refugee Women Connect~~, local NGOs whose primary function is to provide advice and support for AS&Rs.

Participants

1 Trial participants will be asylum seekers and refugees. This includes those with
2 pre-asylum status; those who have been offered either discretionary or indefinite
3 leave to remain in the UK; those whose applications for leave to remain are
4 pending or have been refused; those with humanitarian protection; those with
5 refugee status; stateless people; and people on the vulnerable person resettlement
6 programme.
7

8
9 The other inclusion criteria are:

- 10 • Aged ≥ 18 years (self-reported).
- 11 • Score of ≥ 8 on either the depression or anxiety subscale of The Hospital
12 Anxiety and Depression Scale (HADS)³¹, and score of ≥ 17 on the World
13 Health Organisation Disability Assessment Schedule 2.0 (WHODAS)³².
- 14 • Have conversational English, as self-assessed by the potential participant.
- 15 • Registered with a general practitioner (GP) in Liverpool City Region.
- 16 • Willing to provide relevant socioeconomic data.
- 17 • Provided written informed consent.

18
19 The exclusion criteria are:

- 20 • New arrivals to the UK (less than 28 days), due to high likelihood of
21 dispersal outside the region.
- 22 • In reception centres, usually known as Initial Accommodation, and
23 receiving temporary financial support under Section 98 of the Immigration
24 and Asylum Act 1999 for less than 28 days, also due to high likelihood of
25 dispersal outside the region.
- 26 • Imminent risk of suicide: assessed by researchers using formal protocols
27 with supervision and arbitration from qualified healthcare professionals.
- 28 • Complex mental disorder (bipolar disorder/manic depression, or
29 schizophrenia): Assessed by researcher on basis of: participant self-
30 reporting a diagnosis; and/or participant currently in receipt of
31 antipsychotic medication, defined as medication listed in British National
32 Formulary Chapter 2 section 2.3 (bipolar disorder and mania) and section
33 2.6 (psychoses and schizophrenia). If required, further clinical assessment
34 will occur using standard formal protocols.
- 35 • Cognitive impairment (moderate/severe intellectual disability, any
36 dementia). Assessed by researcher on basis of participant or carer self-
37 report.
- 38 • Substance misuse: assessed by researcher on basis of participant response
39 to the question: 'are you currently having problems with alcohol, cocaine,
40 marijuana or any other drugs?' If response is yes or equivocal, then
41 participant will be excluded. If required, further clinical assessment will
42 occur using standard formal protocols.
- 43 • Currently receiving a formal psychological therapy, to avoid potential
44 confounding effects.

Outcome measures

Specific outcome measures, which are candidates for inclusion in any future definitive trial of PM+ for AS&Rs, will be tested as part of PROSPER Pilot. These are summarised in Table 1 below.

Table 1: PROSPER Outcome Measures

Objective	Outcome Measures	Timepoint(s) of evaluation
Efficacy:		
Severity of combined anxiety and depressive symptoms	Hospital Anxiety and Depression Scale (HADS) ³¹	Baseline, 13 week and 26 week follow up assessments
Functional impairment	WHO Disability Assessment Schedule (WHODAS) ³²	
Subjective wellbeing	WHO-5 Wellbeing Index ³³	
Progress with problems for which participant has sought help	Psychological Outcomes Profile (PSYCHLOPS) ³⁴	
Post-traumatic Stress Disorder (PTSD)	Post-traumatic Stress Disorder Checklist for DSM-5 (PCL-5) ³⁵	
Depressive Disorder	9-item Patient Health Questionnaire (PHQ-9) ³⁶	
Health Economics:		
Use of services and supports from NHS, social care and voluntary sectors	Adapted Client Service Receipt Inventory (CSRI) ³⁷	Baseline, 13 week and 26 week follow up assessments

- HADS is a well-established 14-item scale consisting of 2 subscales: HADS-A (anxiety; 7 items; possible score range, 0-21) and HADS-D (depression; 7 items; possible score range, 0-21). Higher scores indicate more anxiety and/or depression. HADS has been widely used across cultures; it is sensitive to change over time and has good internal consistency, reliability and validity³⁸.
- WHO-5 is validated in international studies for both clinical and psychometric properties and available in many languages.

- WHODAS is applicable across all health states including mental disorders. It has good validity in terms of internal consistency, test-retest reliability, and agreement with other measures of disability across countries.
- PSYCHLOPS has internal consistency, convergent validity with measures of emotional distress, and is sensitive to change. It covers 3 domains: problems (2 questions), functioning (1 question), and well-being (1 question).
- PCL-5 has good psychometric properties for diagnostic accuracy and internal consistency.
- PHQ-9 is based on DSM-IV depression diagnostic criteria. Total severity score ranges from 0 to 27, with 10 as conventional cut-off to diagnose depressive disorder.
- The CSRI has been adapted for the PROSPER trial to include health, social care and voluntary services with the potential to be used by asylum seekers and refugees.

Other elements of PROSPER Pilot will be assessed and used to inform the feasibility of conducting a full trial, as specified in Table 2:

Table 2: PROSPER feasibility measures

Objective	Outcome Measure	Timepoint(s) of evaluation
To assess the feasibility of the proposed procedures for recruiting distressed AS&Rs as study participants	Number of AS&Rs recruited	Baseline
To assess feasibility of randomisation	Successful randomisation of participants	Baseline (randomisation)
To assess the feasibility of retaining study participants through to trial completion	Number of study participants in the trial (assessed in individual arms)	26 weeks
To assess the acceptability and utility of specified primary and secondary outcome measures	Completion of study measures and estimation of between group differences Evaluation of outcome measures	Baseline, 13 weeks, 26 weeks

The feasibility of progression to a definitive multi-centre randomised controlled trial will be informed by the extent to which the criteria below have been met using a go, amend, stop system, as specified in Table 3:

Table 3: PROSPER Progression Criteria

Progression Criteria	Go	Amend	Stop
Recruitment of trial participants	≥70% of target	50-69% of target	<50% of target
Retention of trial participants	≥70% retained	50-69% retained	<50% retained
Protocol adherence	≥70% of intervention delivered per protocol	50-69% of intervention delivered per protocol	<50% of intervention delivered per protocol
Completion of outcome measures	≥70% of measures are complete	50-69% of measures are complete	<50% of outcome measures are complete

If criteria meet ‘amend’ targets, reasons for this will be investigated with an aim to identify aspects amenable to change. If criteria meet ‘stop’ targets, reasons will be analysed and discussion within the project management group and with independent oversight committees. If it is determined that these rates cannot be improved then a full trial will not be recommended.

Other progression criteria involving data from PROSPER Pilot that will be assessed by the research team are:

- Recruitment of supervisors and lay therapists
- Retention of lay therapists
- Acceptability of outcome measures
- Whether clinically important improvement in outcomes are plausible.

Intervention

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

1 Problems (using problem solving techniques); (iii) Get Going, Keep Doing (applying
2 behavioural activation techniques); and (iv) Strengthening Social Support. These
3 strategies are applied by participants during the intervention session to problems
4 they are facing. Each strategy is reviewed in subsequent sessions, with application
5 of strategies between sessions encouraged to enhance learning through repetition.
6 The final session involves a revision of learning, education on preventing relapse,
7 and (for group PM+) ends with a culturally appropriate closing ceremony.
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10 To enhance accessibility for groups, the group PM+ intervention is structured
11 around locally relevant and appropriate pictorial materials and adopts a narrative
12 format to support engagement and individual disclosure of personal difficulties
13 which can be more difficult in a group format. Specifically, a case example of a
14 woman or a man (depending on the gender of group participants) experiencing
15 common functioning and emotional problems is shared each week, with
16 participants following their progress through PM+ Group.
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22 All PM+ sessions will take place at mutually convenient and safe locations, where
23 support is available if required. Sessions will be delivered within organisations
24 which have on-site staff with experience and training in managing emotional
25 distress. No face-to-face sessions will take place in the home of either a
26 participant or lay therapist. **There will be no special criteria for discontinuing or
27 modifying allocated interventions.**
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32 *Protocol adherence*

33
34 Consistent with an apprenticeship model³⁹, protocol adherence is ensured through
35 regular (at least fortnightly) supervision of the lay therapists provided by two
36 Wellbeing Mentors. Involving all individual or group lay therapists in a group,
37 supervision will last up to three hours and will entail reviewing the progress of
38 intervention delivery, including case-management of participants and additional
39 refresher training on intervention components. The group PM+ lay therapists will
40 receive the same as individual PM+ lay therapists, in addition to refresher training
41 on group facilitation skills, through role-play.
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47 The Wellbeing Mentors are in turn provided supervision by one of the Master
48 Trainers, conducted at least monthly during the trial and lasting two hours. In
49 addition, Wellbeing Mentors will have the day-to-day support of their line manager
50 at PSS who also participated in the 5-day PM+ training with Master Trainers, and
51 who participates in the monthly supervision sessions with the Master Trainer to
52 ensure supervision consistency.
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57 Intervention fidelity will be monitored through independent observations of 15% of
58 randomly selected sessions of each lay therapist against tailored checklists,
59 conducted by the Wellbeing Mentors. Session logs (per participant) will be
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1 completed by lay therapists after each PM+ session and will capture information
2 regarding timing, length and content of sessions. The logs will be passed to the
3 Wellbeing Mentors at weekly supervision meetings. A small number of sessions may
4 be audio- or video-recorded as an additional assessment of intervention fidelity.
5 Feedback from intervention observations will be used in subsequent supervision
6 sessions to improve adherence to intervention protocols.
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11 Intervention compliance by trial participants will be measured by assessing
12 adherence to the PM+ protocol with regards to attendance at sessions.
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14

15 *Control arm*

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17 Participants randomised to the control arm will not be offered any PM+ but will be
18 able to access all usual care and support offered by the participating NGOs. To
19 control for the weekly contact that the active arms will receive, participants
20 randomised to the control arm will be invited by the interviewing researcher
21 to attend a local AS&R NGO of their choice. They will be put in contact with other
22 AS&Rs from similar backgrounds and encouraged to meet together on a weekly
23 basis for five weeks.
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28 *Participant Identification*

29
30 Potential participants will be identified primarily through NGOs and primary care
31 teams, all designated as Participant Information Agencies (PIAs). PIAs will be
32 provided with a short summary of the study including the main inclusion and
33 exclusion criteria. They will be asked to display posters and leaflets and discuss
34 the study opportunistically with AS&Rs who access the services. All participant-
35 facing documentation will have the necessary approvals from a Research Ethics
36 Committee.
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41 Potential participants will be made known to the research team via one of the
42 following methods:
43

- 44 • By them contacting the research team directly via telephone or email;
 - 45 • By agreeing to their details being given to the research team (via a
46 participant recommendation form, completed by the PIA with the AS&R, and
47 returned to the research team by the PIA);
 - 48 • By attending a researcher-attended drop-in session at collaborating NGOs on
49 a specific date/time, advertised by posters/leaflets/verbally
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54 Following identification of a potential participant, a postdoctoral researcher based
55 in the University of Liverpool, who is trained in the PROSPER trial techniques and
56 in discussion about informed consent, will arrange a meeting to give more
57 information about the trial.
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Informed Consent

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2 The researcher will contact the potential participant to arrange an individual face-
3 to-face meeting. This meeting will be arranged at the convenience of the AS&R
4 where possible and can be attended by an interpreter if required. The meeting will
5 last between one and two hours. It will take place at a convenient location which
6 could include one of the NGO centres, a community centre, a counselling centre,
7 NHS premises and the University of Liverpool.
8
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10
11 Objectives, risks and inconveniences of the trial and the conditions under which it
12 is to be conducted will be provided by the researcher. All potential participants
13 will be given the opportunity to ask any questions that may arise, will have the
14 opportunity to discuss the study with others and be given time to consider the
15 information prior to agreeing to participate. It will be made clear to the
16 participant that an eligibility assessment will be conducted once consent is given
17 and that if the participant is found to be ineligible for any reason that they will be
18 unable to participate.
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24 The potential participant will be asked to read and review the Participant
25 Information Sheet (PISC), which is available in English and the study languages of
26 Farsi, Urdu, and Arabic. Upon reviewing the document, the researcher will explain
27 the research study to the potential participant. The PISC and the discussion with
28 the participant will emphasise that participation in the trial is voluntary and that
29 the participant may withdraw from the trial at any time and for any reason.
30 **Participants will also be asked for permission for the research team to share**
31 **relevant data with people from the Universities taking part in the research or from**
32 **regulatory authorities, where relevant. This trial does not involve collecting**
33 **biological specimens for storage.** The researcher is aware of the sensitive nature of
34 the research topic and will minimise any distress caused to potential participants
35 as a result of the discussions.
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43 If the asylum seeker or refugee decides that they would like to participate, he or
44 she will then personally sign and date the informed consent document. The
45 document will then be signed and dated by the person obtaining consent. A copy of
46 the informed consent document will be given to the potential participant for their
47 records. The original document will be maintained by the research team separate
48 from any personal identifiable information collected for any participants. A further
49 copy will be sent to the Liverpool Clinical Trial Centre (LCTC) via secure methods if
50 the participant is eligible for full trial participation; this will be sent separately
51 from any participant data subsequently collected. **The PISC (which includes**
52 **informed consent documentation) is available from the corresponding author on**
53 **request.**
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1 If the potential participant requires more time to consider involvement in the trial
2 a further meeting can be arranged at the discretion of the researcher. If the
3 individual does not wish to take part, their reason for not providing consent will be
4 recorded on the PROSPER Screening Log. Once consent has been given the
5 participant may, without being subject to any resulting detriment, withdraw from
6 the trial at any time by revoking the informed consent.
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10 11 12 *Eligibility and baseline assessments*

13 Once written informed consent has been obtained, the potential participant can be
14 assessed for eligibility, as per the criteria detailed above.
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18 Eligibility assessment will follow a staged process. The researcher will review
19 responses at the end of each stage, and if the potential participant is found to be
20 ineligible they will be informed of this and there will be no requirement for
21 completion of the next stage.
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25 Firstly, through discussion with the potential participant, the researcher will
26 complete sociodemographic questions. The researcher will then assess the
27 following exclusion criteria: complex mental disorder (bipolar disorder/manic
28 depression, or schizophrenia); cognitive impairment (moderate/severe intellectual
29 disability, any dementia); substance misuse; currently receiving a formal
30 psychological therapy. If the potential participant remains eligible, they will be
31 asked to self-complete the HADS, WHODAS and PHQ-9 questionnaires within the
32 Eligibility Questionnaire Booklet. These questionnaires are all available in English,
33 Arabic, Farsi and Urdu. The researcher will review the completed PHQ-9
34 questionnaire to assess whether the potential participant is at imminent risk of
35 suicide. If there are any concerns regarding suicide risk, the researcher will follow
36 the procedure outlined in the Suicidal Ideation Guidance Document.
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44 If the potential participant is eligible following this process, the researcher will
45 conduct the baseline assessments outlined in the following section. This will allow
46 consistency for outcome measurement completion, and also reduce the need for
47 attendance at additional meetings. If the researcher has any concerns or
48 uncertainties from the non-clinical eligibility assessment above, they will contact
49 the Chief Investigator (CI) or nominated deputy to discuss the case.
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54 AS&Rs who are assessed as ineligible can be reconsidered for participation at a
55 later date if circumstances change e.g. if they are able to register with a GP. If
56 this is more than two weeks after consent was obtained, the consent process will
57 be repeated.
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Following the completion of the eligibility assessment, the researcher will ask the eligible participant to self-complete the Baseline Questionnaire Booklet, which incorporates the remaining baseline assessments: the WHO-5, PSYCHLOPS and PCL-5 questionnaires. The CSRI Form, which has been adapted for PROSPER, will be completed by the researcher through discussion with the participant.

For a potential participant who completes the eligibility assessment process and is deemed eligible to participate in PROSPER Pilot, but where there was concern or uncertainty that necessitated the researcher contacting the CI or nominated deputy, the CI or nominated deputy will review the information provided by the participant to verify eligibility for trial participation and complete the Eligibility and Baseline CRF before randomisation occurs.

Randomisation

Participants will be randomised using a secure web-based randomisation program. Randomisation lists will be generated in a 1:1:1 ratio, to individual PM+, group PM+ and control, using block randomisation with random variable block sizes.

The randomisation list will be generated by a statistician independent to the PROSPER trial. Given the open nature of the trial, it will not be possible to blind researchers, trial participants, care providers, outcome assessors or data analysts to the intervention arm to which participants are assigned.

The researcher will update the PROSPER Screening Log when a participant has been randomised. The researcher will be responsible for notifying the participant of their allocation. In the event that a participant is randomised individual or group PM+, the researcher will inform the PSS Lead. Intervention delivery will be coordinated by PSS in collaboration with the participant and their lay therapist. The research team will notify the participant's GP by letter of their enrolment into the trial and to what treatment arm they have been allocated.

Assessments and Follow-up

All assessments and follow up will be conducted in line with the Schedule of Assessments summarised in Table 4

Table 4. Schedule of Assessments

	Screening and Baseline	Randomisation	13 week follow up	26 week follow up
Timepoint (weeks)	0	0	13±2	26±2
Procedures:				

Consent, Eligibility screening and confirmation				
Written and Informed Consent	X			
Assess Eligibility	X			
Confirm Eligibility	X			
Randomisation		X		
Confirm Consent		X	X	X
Data Collection				
HADS	X		X	X
WHODAS	X		X	X
PHQ-9	X		X	X
PSYCHLOPS	X		X	X
PCL-5	X		X	X
WHO-5	X		X	X
CSRI	X		X	X
Adverse Events				
Assessment of AEs	X		X	X

In the case of premature discontinuation/withdrawal, there are no additional assessments for participants.

All specified outcomes will be measured at 13 (± 2) and 26 (± 2) weeks post-baseline. 13 weeks will be the primary end point: this is consistent with previous trials (Rahman et al, 2016). It allows time for intervention delivery and often may correspond to the timings of Home Office decisions on leave to remain for asylum seekers.

Follow Up Visit 1 - 13 week follow up

This is expected to be a face-to-face appointment at 13 weeks ± 2 weeks from baseline, and include:

- Verbal confirmation of continued consent;
- The participant will complete the following questionnaires within the Follow Up Questionnaire Booklet: HADS, WHODAS, PHQ-9, WHO-5, PSYCHLOPS, PCL-5;
- If suicidal ideation is disclosed or suspected, the researcher will follow the steps outlined in the Suicidal Ideation Guidance document;
- Recording of any adverse event information;
- Researcher-led completion of the adapted CSRI;
- Completion of Follow Up CRF

Follow Up Visit 2 - 26 week follow up

1 This is expected to be a face-to-face appointment at 26 weeks \pm 2 weeks from
2 baseline, and to follow the same process as the follow up appointment at 13
3 weeks.
4

5 All follow up appointments will be coordinated and conducted by the trained
6 researcher. They will conduct a preliminary review of the data collected to screen
7 for missing data or any responses that may need further follow up or clinical
8 discussion. Follow up appointments are expected to take around 1 hour which
9 should allow for completion of all data collection and review of any adverse
10 events. If a face-to-face appointment cannot be arranged during the follow up
11 window then the visit can be conducted by telephone if possible. If the research
12 team are unable to make arrangements to administer the assessments, the option
13 of the participant self-completing the assessments and returning them by post will
14 be explored. It is expected that participant responses will be completed during the
15 appropriate visit window.
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22 The PROSPER Pilot study design is summarised in Figure 1.
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25 **Figure 1: Schematic of Study Design [include near here]**
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31 *Statistical considerations*

32 A detailed statistical analysis plan (SAP) will be developed prior to the first
33 comparative monitoring report to be presented to the Independent Data and
34 Safety Monitoring Committee (IDSMC). The main features of these planned
35 statistical analyses, which refer specifically to the PROSPER pilot, are detailed
36 below.
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40
41 The aim is to recruit 105 participants, 35 to each of three arms - individual PM+,
42 group PM+ and control. Individual sessions will be offered as gender- and language-
43 specific, i.e. the lay therapist and the study participant will be the same gender
44 and will be comfortable in a common language. At least four groups will be offered
45 for the group intervention, each with up to 8 or 9 participants, each gender-
46 specific, i.e. participants will all be the same gender and at least one of the lay
47 therapists will be of the same gender as the participants.
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52 The sample size needs to be sufficient to estimate retention levels in a definitive
53 trial. With an expectation of 80% retention, samples of 35 participants for each of
54 the individual, group and control arm will provide an accurate estimate of
55 retention \pm 13% (67% to 93%).
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1 Retention rates will be assessed in each arm separately, as there may be
2 systematic differences between them; for example, those randomised to the
3 control arm may be less likely to remain engaged than those randomised to the
4 individual or group arms, while those randomised to the group arm may be
5 demotivated if faced with a lengthy wait for their group to begin.
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7
8 No formal interim analysis is planned as this is a pilot study and there are no
9 anticipated problems that are detrimental to the participant. There will be
10 monitoring by the IDMSC, who will provide a recommendation to the Trial Steering
11 Committee (TSC) on the continuation of the trial.
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15 Analysis will be by the intention-to-treat principle as far as is practically possible.
16 All analyses will be descriptive, focussed on assessing the criteria for deciding
17 whether to progress to a full trial. All estimates of proportions will be presented
18 with 95% confidence intervals. Rates of recruitment and attrition will be presented
19 both for lay therapists and trial participants, along with the proportion of PM+
20 interventions which are successfully delivered per protocol. The proportion of
21 missing data in the proposed trial outcome measures will be assessed.
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26 Preliminary exploration of estimates of efficacy will involve a group-wise
27 comparison of the primary outcome: severity of combined anxiety and depressive
28 symptoms at 13 weeks post-baseline measured using the Hospital Anxiety and
29 Depression Scale.
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33 Socio-demographic data, and use of services and supports will be captured by the
34 adapted Client Service Receipt Inventory³⁷. This data can be used for a wide range
35 of applications, including estimating the costs of service receipt and societal costs.
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39 No formal testing of intervention effect will be carried out, but estimates of
40 between group differences between the test groups and the control in outcome
41 measures will be presented, with 95% confidence intervals, to assess whether a
42 clinically important improvement in outcome would be plausible in a full trial. The
43 effect of clustering by intervention provider on outcomes in the two PM+ groups
44 will be investigated, to inform design of a full trial with a partially nested design.
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49 *Process Evaluation and Feasibility Assessment*

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51 Relevance and acceptability of proposed outcomes will be tested, with a view to
52 their incorporation or refinement for a definitive trial. These will include:
53

- 54 • Effectiveness of PM+, based on the primary outcome of combined HADS scores;
 - 55 • Cost-effectiveness of PM+ from an NHS perspective, based on the primary
56 outcome of combined HADS scores^{40,41}.
 - 57 • Cost benefit from a societal perspective, given that costs and potential benefits
58 will extend beyond the NHS to local government and voluntary sectors⁴²⁻⁴⁴.
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- Impact on health inequalities using the NIHR CLAHRC NWC Health Inequalities Assessment Toolkit (www.hiat.org.uk): first, within AS&R communities in relation to age, gender, nationality, education, prior occupation and asylum status; and second, between AS&Rs and national populations, comparing mental health status (anxiety, depression PTSD and wellbeing) with UK population norms, with reference to published psychiatric morbidity data⁴⁵.

The feasibility of the 13- and 26-week time points will be assessed, with specific reference to rates of participant attrition.

Researchers will undertake a systems-based *process evaluation*⁴⁶, beginning three months into the PROSPER Pilot, to: understand service provider and participant experiences and perspectives on acceptability, efficiency, implementation and development of PM+; understand service-users' perceptions and experiences of accessing and participating in PM+; explore how PM+ fits into existing health/social care systems; and understand change process dynamics including barriers and facilitators to implementing PM+. An ethnographic method will be adopted including observation of PM+ implementation alongside semi-structured interviews and focus group discussions with key stakeholder groups such as lay therapists, Wellbeing Mentors, PM+ participants, representatives from NGOs working with AS&R communities, health professionals and commissioners from Liverpool City Region. Heterogeneity within the population will be considered and whether the intervention's feasibility and effectiveness may differ by demography or asylum status, and how this may influence the choice of target population for our proposed definitive trial.

Analysis will be based on narrative synthesis, combining data tabulation and narrative techniques. This will involve iterative review and refinement in order to reach agreement on a set of general propositions in relation to the data. The perspectives of Normalisation Process Theory^{47,48} will be used to assess the potential for implementing a full randomised controlled trial, focussing on the progression criteria set out above.

Discontinuation and withdrawal

In consenting to the trial, participants agree to all trial activities including administration of trial intervention and follow-up assessments / visits and data collection. Every effort will be made to facilitate the completion of these for every recruited participant. If it is not possible to complete these activities (or it is deemed inappropriate) the reasons why should be documented.

Participants may discontinue the study intervention for reasons including, but not limited to:

- Participant-led i.e. request by the participant

- Researcher/Clinician/Lay therapist-led:
 - Any change in the participant's condition that justifies the discontinuation of the intervention in the researcher/clinician/lay therapist's opinion;
 - Reasons of non-adherence or non-compliance with study intervention or other trial procedures e.g. unable to complete course of PM+;
 - Participant meets an exclusion criterion (either newly developed or not previously recognised).

Discontinuation from PM+ does not mean discontinuation of the study altogether, and the remaining study procedures i.e. 13- and 26-week follow up visits and data collection, and process evaluation, will be completed as indicated in the protocol (unless consent is specifically withdrawn).

Participants are free to withdraw from follow up at any time without providing a reason, though a reason should be recorded if one is given. Those who wish to withdraw from further follow-up will have the data collected up to the point of that withdrawal included in the analyses. The participant will not contribute further data to the study and the LCTC will be informed, via email to the LCTC and via completion of a Withdrawal CRF to be returned to the LCTC within 24 hours. Death of a participant would be recorded on a Withdrawal CRF and a Death CRF.

For participants moving from the area, every effort will be made for the participant to be followed-up and to complete their remaining study appointment(s) remotely.

A participant will be considered lost to follow up if s/he fails to return for any scheduled visits and is not contactable by the site research team. If a participant fails to attend/facilitate a required study visit the following actions must be taken:

- The researcher will attempt to contact the participant and reschedule the missed visit (be conscious of acceptable windows for collecting valid data) and advise the participant on the importance of maintaining the assigned visit schedule.
- Before a participant is deemed to be lost to follow up, the research team will make reasonable effort to regain contact with the participant.
- If the participant continues to be unreachable they should be considered withdrawn from the study with a primary reason of lost to follow up and this should be recorded on the Withdrawal CRF.

Confidentiality and access to data

Forms which contain participant identifiers will be stored separately from the case report forms (CRFs). The database will be secured with password-protection.

1 Participants' data will not be released outside of the study without the written
2 permission of the participant, documented in the consent form.

3
4 The University of Liverpool and Bangor University are registered as data controllers
5 with the Information Commissioner's Office.
6

7 8 *Safety and monitoring* 9

10 Safety assessments will be based on information disclosed by the participant
11 throughout trial duration and by those who have knowledge of their welfare,
12 including GPs, other health professional and NGO members. The Chief Investigator
13 and other research staff are responsible for monitoring and reporting all adverse
14 events.
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18 Ancillary and post-trial care will be the responsibility of the participant's registered
19 general practitioner.
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22
23 Data will be centrally monitored by the LCTC to promote data quality. Monitoring
24 processes are documented in the 'Trial Monitoring Plan' and can be made available
25 from the authors on request. If necessary, on-site monitoring visits can be
26 triggered and will be carried out by either the LCTC or the sponsor representative.
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30 Safety information and data will be independently monitored by the IDSMC. The
31 IDSMC is chaired by an independent senior clinical academic, and includes an
32 independent methodological expert and an experienced service user. The IDSMC
33 will report to the TSC, and hence to the NIHR Public Health Research Programme
34 Board. The composition and terms of reference for both the IDSMC and the TSC are
35 available from the authors on request.
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39 40 *End of trial* 41

42 The end of the trial is defined to be the date on which data for all participants is
43 locked and data entry privileges are withdrawn from the trial database. However,
44 the trial may be closed prematurely by the TSC on the recommendation of the
45 IDSMC.
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49 50 *Dissemination* 51

52 Using established procedures for knowledge exchange we will disseminate the
53 findings of our research through:

- 54 • Dedicated project web-page and social media sites;
- 55 • Feedback to participants, both service users and providers;
- 56 • Presentations to stakeholder groups including service users and providers,
57 policy makers and commissioners, funders and benefactors;
- 58 • Presentations to national asylum seeker and refugee NGOs;
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- Presentations at clinical academic conferences;
- Report for NIHR Public Health Research journal;
- Submission of research papers to high impact peer reviewed journals.

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Discussion

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3 The PROSPER feasibility study and pilot trial will generate new knowledge of
4 benefit to the health service and to society. This study will ascertain whether lay
5 therapists based in NGOs can be trained to deliver PM+ with demonstrable
6 evidence of capacity. It will provide early indications whether PM+ can lead to
7 improvements in mental health and function for distressed AS&Rs in current UK
8 settings. It will identify potential new pathways for access to care for these
9 vulnerable groups, overcoming existing barriers such as accessibility of delivery
10 locations and language barriers.
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16 There is currently a lack of evidence on feasibility of conducting research into
17 psychosocial interventions in these circumstances, and this study will address this
18 gap in the evidence-base. We anticipate that the study will provide clear evidence
19 on the key parameters needed for a definitive randomised controlled trial in this
20 field. Such a definitive trial has the potential to improve mental health, wellbeing
21 and functional ability amongst AS&Rs, and to reduce health inequalities. This is
22 likely to lead to more equitable and effective use of health care, with a shift from
23 receiving emergency care to managed, proactive and preventive care. From a
24 societal perspective, cost effectiveness and cost-benefit analyses following the
25 definitive trial will indicate the extent to which the intervention confers both
26 direct and indirect benefits. Public and patient involvement will ensure that the
27 project delivers high quality, original evidence that has the potential to have a
28 significant impact on the design of the definitive intervention and, subsequently,
29 on policy and practice.
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37 From an international perspective, our findings will have relevance for other HICs
38 hosting refugees, as well as for WHO recommendations on the use of PM+ with
39 AS&R communities who experience significant adversities.
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Trial status

- 47 • Protocol version V5.0 Dated: 11/12/2019
 - 48 • Recruitment start: 27/11/2019
 - 49 • Recruitment completion (expected): 31/05/2020
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List of abbreviations

AE	Adverse Event
AS&R	Asylum Seeker and Refugee
CI	Chief Investigator
CRF	Case Report Form
CSRI	Client Service Receipt Inventory
DSM-5	Diagnostic and Statistical Manual of Mental Disorders (5 th edition)
GP	General Practitioner
HADS	Hospital Anxiety and Depression Scale
HIC	High Income Countries
HRA	Health Research Authority
IAPT	Increasing Access to Psychological Therapies
IDSMC	Independent Data and Safety Monitoring Committee
LCTC	Liverpool Clinical Trials Centre
LMIC	Low and Middle Income Countries
NGO	Non-Governmental Organisation
NHS	National Health Service
NRES	National Research Ethics Service
NIHR CRN	National Institute for Health Research Clinical Research Network
PHQ-9	9-item Patient Health Questionnaire
PI	Principal Investigator
PIA	Participant Information Agency
PM+	Problem Management Plus
PMG	Project Management Group
PSS	Person Shaped Support
PSYCHLOPS	Psychological Profiles Instrument
PTSD	Post-Traumatic Stress Disorder
R&D	Research & Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RSI	Reference Safety Information
RSO	Research Support Office
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
TSC	Trial Steering Committee
WHO	World Health Organisation
WHO-5	World Health Organisation Five Wellbeing Index
WHODAS	World Health Organisation Disability Assessment Schedule

Declarations

- The PROSPER trial is funded by the National Institute for Health Research Public Health Programme (Ref: 17/44/42)
- The trial protocol and other trial-specific documentation have received the favourable opinion of the North West - Liverpool Central Research Ethics Committee (Ref: 19/NW/0345). Any subsequent protocol amendments will be submitted for ethical approval.
- The University of Liverpool is the sponsoring organisation (email sponsor@liverpool.ac.uk; reference UoL 0014690). It will formally delegate specific trial activities to the Chief Investigator and Liverpool Clinical Trials Centre (LCTC), but remains legally responsible for the trial.
- All named authors adhere to the authorship guidelines of Trials. All authors have agreed to publication.

Consent for publication

- This paper represents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Availability of data and materials

- Fully anonymized participant-level datasets and statistical code can be made available upon reasonable request once the final results of the trial have been published.

Competing interests

- The authors declare no competing interests

Authors' contributions

- CD, AR and RGW conceived of and designed the study, with support from RWA, GB, AC, RTE, MEL, LO, ER, PU and EW. RR and CD drafted the article. All authors contributed to the development and refining of the article, and approved the final submitted version.

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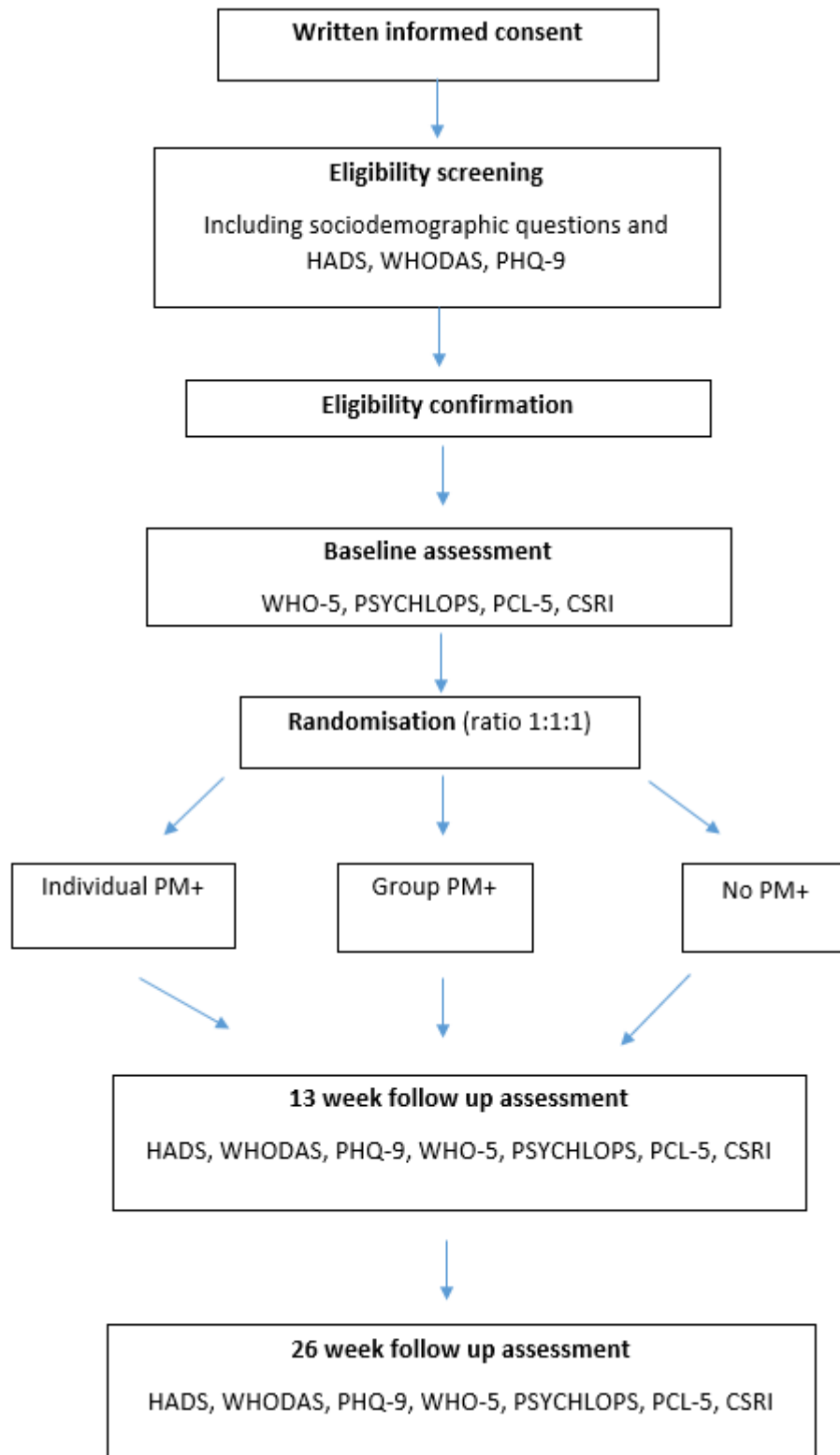
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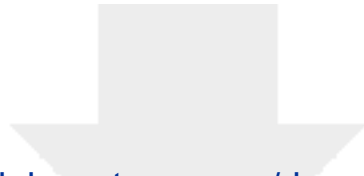
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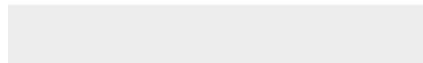
Figure 1: Schematic of Study Design



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Supplementary Material

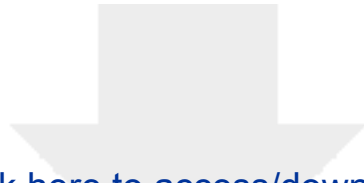
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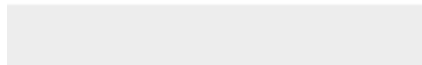


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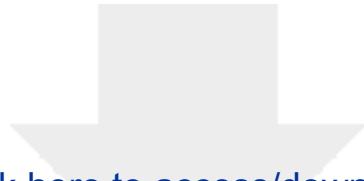


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