Feasibility study and pilot trial of an evidence-based low intensity psychosocial intervention delivered by lay therapists for asylum seekers and refugees (PROSPER)

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Word count: 30,522

Key words: Refugees, asylum seekers, mental health, psychosocial intervention, Problem Management Plus

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Disclosure of interests statement: R White: Grant from European Commission, Horizon 2020 (grant agreement n. 779255) to conduct the Refugee Emergency: DEFining and Implementing Novel Evidence-based psychosocial intervention (RE-DEFINE) project evaluating the effectiveness of SH+ for refugees. The results of the clinical trials are reported in the report.

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The research reported in this 'first look' scientific summary was funded by the PHR programme as project number 17/44/42. For more information visit https://fundingawards.nihr.ac.uk/award/17/44/42

The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors have tried to ensure the accuracy of the authors' work and would like to thank the reviewers for their constructive comments however; they do not accept liability for damages or losses arising from material published in this scientific summary.

This 'first look' scientific summary presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the PHR Programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PHR Programme or the Department of Health and Social Care.

SCIENTIFIC SUMMARY

Rationale

Asylum seekers and refugees (AS&Rs) have high prevalence of psychological morbidity, but encounter extensive barriers to accessing health care. Making psychological therapies more accessible for AS&Rs is a national priority. Problem Management Plus (PM+) is a low intensity trans-diagnostic psychosocial intervention, designed to be delivered by lay therapists. To date there is limited evidence of effectiveness or cost-effectiveness of interventions such as PM+ offered by lay therapists to AS&Rs in high income countries. There is therefore a need to offer and evaluate an accessible intervention, designed to address the mental health and associated practical problems experienced by AS&Rs in the UK.

Aim and objectives

The aim of the PROSPER study was to assess the feasibility of conducting 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.

The objectives were to:

1. adapt the form and content of PM+ to the needs of asylum seekers and refugees in the UK;
2. assess the feasibility of the proposed training procedures, including involvement of refugees as lay therapists;
3. assess the feasibility of the proposed procedures for recruiting distressed asylum seekers and refugees as study participants;
4. assess the feasibility of retaining both lay therapists and study participants through to trial completion;
5. assess the fidelity of delivery of the intervention;

6. assess the acceptability and utility of the proposed study measures, considering any linguistic and cultural barriers;
7. assess how services use data can be measured.

And hence, 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.

Research design

We undertook a feasibility study of PM+, within which we included a pilot study of the design features of a future definitive randomised controlled trial.

The *feasibility study* involved adaptation of PM+, using two parallel and interlinked elements:

- Evidence synthesis to identify the barriers and facilitators to uptake of psychosocial interventions delivered by lay therapists to improve mental health and wellbeing of asylum seekers and migrants.
- Stakeholder engagement with local stakeholders using focus group methodology, to ensure that PM+ is adapted for use with AS&R populations in the UK.

We also assessed the feasibility of a two stage PM+ training procedure, with master trainers providing a training course tailored to the needs of wellbeing facilitators from a counselling NGO, who in turn provided an 8-day training course and ongoing supervision for lay therapists in NGOs that support AS&Rs.

The *pilot trial* was designed to assess:

- Feasibility of recruitment, with procedures based on a partially nested design to adjust for clustering by intervention provider in the test arm, with the client as the unit of randomisation.
- Feasibility of a randomisation procedure, in which participants are randomised using a secure 24-hour web-based randomisation system.
- Feasibility of the proposed delivery model, in relation to three key issues:
    - Retention of lay therapists and study participants;
    - Individual vs. group approaches;
    - Fidelity of intervention delivery.
- Relevance and acceptability of the proposed study measures.

Feasibility Study

Evidence synthesis. We conducted a systematic review of barriers and facilitators to uptake of psychosocial interventions delivered by lay therapists to improve mental health and wellbeing of asylum seekers and refugees. The systematic review followed the guidance of the Centre for Reviews and Dissemination.

Almost 15,000 titles and abstracts were shortlisted for assessment, from which 25 papers were identified as suitable for detailed analysis: 15 qualitative studies, seven trials and three others. Due to the heterogeneity of included studies and the limitations of available data, the findings are presented as a narrative summary:

Barriers for AS&Rs included beliefs about mental health; lack of trust, privacy and sense of safety; sense of isolation and inferiority; uncertainty about legal status; and lack of trained interpreters. Facilitators for AS&Rs included interventions adapted to local context; free-listing of problems; and support from other AS&Rs.

Barriers for lay health workers included problems with the work itself, personal socio-economic problems or working in a hostile environment. Facilitators for lay health workers included team cohesion, social support and supervision. Lay health workers value being recognized as a resource in society.

Stakeholder engagement. Stakeholders, including both service providers and service users, were recruited from asylum seeker and refugee support organisations across Liverpool City Region using purposive sampling via a convenience approach. Twenty-four individuals participated in six focus groups: 16 were women and 8 were men; the age range was 27 to 76 years; 13 were service providers and were 11 service users.

Stakeholders generally expressed positive views about PM+ and its usefulness for distressed asylum seekers and refugees. They identified potential advantages over existing service provision, which was often seen as difficult to access. They saw delivery of PM+ as beneficial for lay therapists themselves, as well as for their clients. Some stakeholders raised questions about the scripted nature of PM+, and raised concerns about lay therapists going beyond the limits of PM+. Others questioned the therapy orientation of PM+.

Barriers to implementing PM+ included busy lives of AS&Rs, threat of dispersal, cultural differences, gender issues, and confidentiality. Facilitators included initial contact by phone, locating sessions in a safe environment, emphasising confidentiality, matching therapist and client for gender, and perhaps for language and culture.

Training procedures. The PM+ training adopts a cascade apprenticeship model, where Master Trainers train and supervise Wellbeing Mentors; who subsequently train and supervise the lay therapists. Two Wellbeing Mentors were recruited and trained through a local voluntary organisation. Twelve people with lived experience of the asylum process took part in the lay therapist training programme: seven were female, most aged 30 to 40; at least seven were educated to graduate level; native languages were Urdu (4), Farsi (3), Arabic (2) and one each

Turkish, Thai and English/French. Training was provided over eight days in either group or individual PM+, followed by practice cases, and was completed by 11 people.

We highlighted logistical challenges when working with refugee and asylum-seeking lay therapists, strategies to promote ongoing lay therapist engagement, and opportunities for team and personal growth. A core learning point was the role of straddling the intervention and research components of the PROSPER study. Supervision and support of lay therapists needed to include boundary issues between therapy and involvement in participants' lives.

Contextual modifications

We therefore proposed the following contextual modifications to promote uptake and relevance of the PROSPER Pilot trial:

- Focus on English, Arabic, Farsi and Urdu, identified as four most common languages currently spoken by AS&Rs in Liverpool City Region.
- Decision to exclude new arrivals and those in temporary accommodation: on grounds of a) high probability of dispersal and hence unavailability for intervention and/or follow-up; and b) low probability of being registered with a GP and hence unable to access trial safeguarding procedures.
- Alteration to text of PM+ manuals to reflect life in western urban settings, rather than south Asian rural settings: e.g. 'home' not 'hut', 'reading' not 'rearing poultry', 'visit job centre' not 'speak with village elder'.
- Adapting the group PM+ case studies to include men.
- Matching therapists and participants on basis of gender and language, but not on basis of religion, politics or culture.
- Identification of accessible 'safe spaces' for research interviews and delivery of PM+ sessions, including availability of child care.
- Reimbursement of travel expenses for lay therapists and participants.

Pilot Trial

Trial design. The PROSPER pilot trial was designed to 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 were measured by Hospital Anxiety and Depression Scale (HADS) and WHO Disability Assessment Schedule (WHO-DAS). We aimed to recruit 105 participants, 35 per arm.

Inclusion criteria were AS&Rs aged 18+, experiencing emotional and practical difficulties, registered with a GP in Liverpool City Region, and able to converse in English. Exclusion criteria were new arrivals in initial accommodation, current psychological therapy, severe mental disorder or cognitive impairment.

Primary health outcomes were anxiety and depressive symptoms at three months, measured by HADS. Secondary outcomes included subjective wellbeing, functional status, progress on identified problems, post-traumatic stress disorder, depressive disorder and service usage. Longer term impact was assessed at six months post baseline, on the same parameters.

The trial objectives were to assess the feasibility of conducting a full RCT in relation to 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.

Preliminary findings. The pilot trial was open to recruitment for 3.5 months, from late November 2019 until the COVID-pandemic lockdown in early March 2020. The main sources of referrals were NGOs associated with the PROSPER project. Twenty people were screened for the pilot trial, of whom eleven were randomised. Participants came from eight different countries, and were resident in UK for between 37 days and ten years; four had leave to remain. Eight (73%) were successfully followed up at three months, and seven (64%) at six months. Descriptive statistics were provided for primary and secondary outcomes, but numbers were too small to draw any meaningful inferences.

Impact of COVID-19

The COVID-19 pandemic meant that the pilot trial was brought to a halt in March 2020. On the basis of national responses to the pandemic, to have the option to continue we proposed the following substantial protocol amendments:

- Add options for remote recruitment including consent and baseline assessment.
- Expand recruitment options by removing the exclusion criteria regarding initial accommodation and involving primary care teams as participation identification centres.
- Include COVID-related questions at assessment and follow-up.
- Pause the group intervention while social distancing measures are in place.
- Add option for remote delivery of individual intervention.
- Offer follow up at primary end point to all participants.

However, it was not possible to continue or complete the pilot trial as planned.

Health economics evaluation – measuring service use

We received limited data (N=12) and we are unable to make any observations about burden of cost. However, the Client Service Receipt Inventory (CSRI) performed well in terms of completion across three time points and with no negative feedback from participants or researchers.

Process evaluation

A process evaluation was undertaken during and after the COVID lockdown, exploring stakeholder perceptions of the research process and of the intervention delivery. Eighteen stakeholders took part, either in an open meeting, a focus group or an individual interview.

Research process. Barriers to recruitment included delays due to COVID, complexity of referral processes involving multiple agencies, discomfort within NGOs about randomisation to control, problems with trust and stigma, working across cultures with different concepts of mental health. Recruitment could be facilitated by building trust, ensuring culturally

appropriate research instruments, greater financial incentives and more involvement of GPs. Remote working was also seen to have potential advantages.

Intervention delivery. The service user found gender matching helpful. The lay therapists reported that benefited their own mental health, operating as a cohesive group with a clear sense of purpose. They enjoyed working across different cultures but found some challenges operating with different languages, and in coordinating the study with their other roles.

Summary of findings against objectives

1. The form and content of PM+ was successfully adapted to meet the needs of asylum seekers and refugees in the UK. key findings from evidence synthesis and stakeholder engagement integrated to provide relevant contextual modifications.
2. The feasibility of the proposed training measures was fully demonstrated, including the involvement of refugees as lay therapists.
3. Preliminary data were gathered on the feasibility of proposed measures for recruiting distressed asylum seekers and refugees as study participants. Initial observations were that this needs considerable investment of energy and time, and that most effective recruitment procedures may be through involved NGOs where levels of trust are highest.
4. The feasibility of retaining lay therapists was demonstrated: by the end of the study, despite considerable delays, six were still actively engaged. There was preliminary evidence of the feasibility of retaining study participants at both follow up points.
5. There was preliminary evidence of fidelity of intervention delivery, on the basis of assessment of eight individual PM+ sessions delivered by two lay therapists.
6. There was preliminary evidence of the acceptability and utility of the proposed study measures, although concerns were noted about the complexities of operating across multiple languages, and conceptual issues for mental health questionnaires.
7. Measurement of service use questionnaire (CSRI) performed well across those completed (N=12) and could be developed further for a full trial.

Conclusions

Given the early termination of the pilot trial, it was not possible to specify the parameters for a full RCT to test the effectiveness and cost-effectiveness of PM+ as an intervention for distressed and functionally impaired asylum seekers and refugees in the UK.

We demonstrated that the form and content of PM+ can be adapted to meet the needs of asylum seekers and refugees, and that asylum seekers and refugees can be successfully trained as lay therapists to deliver this low intensity psychosocial intervention in local AS&R communities. We were also able to offer guidance on strategies for recruitment and retention of trial participants, and on acceptability and utility of study measures, which may be of value in future studies of this nature.

Funder and Trial registration:

The trial was funded by the NIHR Public Health Research programme (Funder reference 17/44/42), and was registered with the ISRCTN, registration number ISRCTN15214107.