The Problem Management Plus psychosocial intervention for distressed and functionally impaired asylum seekers and refugees: the PROSPER feasibility RCT

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Scientific summary

The PROSPER feasibility RCT

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Scientific summary

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Rationale

The prevalence of psychological morbidity among asylum seekers and refugees (AS&Rs) is high, but AS&Rs 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. At present, 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 (RCT) in the UK of an evidence-based psychosocial intervention based on PM+, delivered by lay therapists for distressed and functionally impaired AS&Rs.

The objectives were to:

- adapt the form and content of PM+ to the needs of AS&Rs in the UK
- assess the feasibility of the proposed training procedures, including the involvement of refugees as lay therapists
- assess the feasibility of the proposed procedures for recruiting distressed AS&Rs as study participants
- assess the feasibility of retaining both lay therapists and study participants through to trial completion
- assess the fidelity of delivery of the intervention
- assess the acceptability and utility of the proposed study measures, considering any linguistic and cultural barriers
- assess how service use data can be measured.

In working towards these objectives, we aimed to specify the parameters of a full RCT to test the effectiveness and cost-effectiveness of PM+ in reducing emotional distress and health inequalities, and improving functional ability and well-being among AS&Rs.

Research design

We undertook a feasibility study of PM+, which included a pilot study of the design features of a future definitive RCT.

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

- evidence synthesis to identify the barriers to and facilitators of the uptake of psychosocial interventions delivered by lay therapists to improve the mental health and well-being of AS&Rs
- 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 well-being facilitators from a counselling non-governmental organisation (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:

  i. retention of lay therapists and study participants
  ii. individual compared with group approaches
  iii. fidelity of intervention delivery.

- relevance and acceptability of the proposed study measures.

Feasibility study

Evidence synthesis

We conducted a systematic review of the barriers to and facilitators of the uptake of psychosocial interventions delivered by lay therapists to improve the mental health and well-being of AS&Rs. 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 (comprising 15 qualitative studies, seven trials and three others) were identified as suitable for detailed analysis. Owing to the heterogeneity of the included studies and the limitations of the available data, the findings are presented as a narrative summary. The literature search identified the following barriers and facilitators:

- Barriers to the uptake of psychosocial interventions by AS&Rs include 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 of the uptake of psychosocial interventions by AS&Rs include interventions adapted to local context; free-listing of problems; and support from other AS&Rs.
- Barriers to the delivery of psychosocial interventions by lay health workers include problems with the work itself, personal socioeconomic problems and working in a hostile environment. Facilitators of the delivery of psychosocial interventions by lay health workers included team cohesion, social support and supervision. Lay health workers valued having their contributions to the programme recognised.

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 (aged 27–76 years) participated in six focus groups: 16 were women and eight were men; 13 were service providers and 11 were service users.

Stakeholders generally expressed positive views about PM+ and its usefulness for distressed AS&Rs. They identified potential advantages over existing service provision, which was often seen as difficult to access, and saw the delivery of PM+ as beneficial for both lay therapists and 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 the busy lives of AS&Rs, the threat of dispersal, cultural differences, gender issues and confidentiality. Facilitators included initial contact by telephone, locating sessions in a safe environment, emphasising confidentiality, matching therapist and client by gender and, where possible, by language and culture.

Training procedures

The PM+ training adopts a cascade apprenticeship model, whereby master trainers train and supervise well-being mentors, who subsequently train and supervise the lay therapists. Two well-being 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 of these trainees were female, six were aged between 30 and 40 years, and at least seven were educated to graduate level. The native languages spoken were Urdu ($n = 4$), Farsi ($n = 3$), Arabic ($n = 2$), Turkish ($n = 1$), Thai ($n = 1$) and English/French ($n = 1$). Training in either group or individual delivery of PM+ was provided over 8 days, followed by practice cases, and was completed by 11 people.

We encountered several logistical difficulties when working with refugee and asylum-seeking lay therapists. Conducting the intervention alongside research components of the PROSPER study proved challenging, as did the supervision and support of lay therapists (which needed to emphasise the boundary between therapy and involvement in participants' lives). However, we overcame these challenges by identifying opportunities for team and personal growth, and developing strategies to promote ongoing lay therapist engagement.

Contextual modifications

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

- focusing on English, Arabic, Farsi and Urdu, which were identified as the four most common languages currently spoken by AS&Rs in Liverpool City Region
- excluding new arrivals and those in temporary accommodation, owing to there being (a) high probability of dispersal and hence unavailability for intervention and/or follow-up; and (b) low probability of being registered with a general practitioner (GP) and hence unable to access trial safeguarding procedures

- altering the 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 the bases of gender and language (but not on the bases of religion, politics or culture)
- identifying accessible 'safe spaces' for research interviews and delivery of PM+ sessions, including availability of child care
- reimbursing 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 the usual support offered by local NGOs. Distress and impairment at baseline were measured using the Hospital Anxiety and Depression Scale (HADS) and World Health Organization Disability Assessment Schedule (WHODAS). We aimed to recruit 105 participants, with 35 in each arm.

Inclusion criteria for the trial were AS&Rs being ≥ 18 years of age, experiencing emotional and practical difficulties, being registered with a GP in Liverpool City Region and having the ability to converse in English. Exclusion criteria for the trial were AS&Rs new to initial accommodation, or currently receiving psychological therapy, or experiencing severe mental disorder(s) or cognitive impairment.

Primary health outcomes were anxiety and depressive symptoms at 3 months, measured using the HADS. Secondary outcomes included subjective well-being, functional status, progress on identified problems, post-traumatic stress disorder, depressive disorder and service usage. Longer-term impact was assessed at 6 months post baseline using the same parameters.

The trial objectives were to assess the feasibility of conducting a full RCT in relation to the recruitment and retention of lay therapists and study participants, the fidelity of delivery of PM+, and the 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 11 were randomised. Participants came from eight countries and had been resident in the UK for between 37 days and 10 ten years; four had leave to remain. Eight (73%) were successfully followed up at 3 months, and seven (64%) were followed up at 6 months. Descriptive statistics were provided for primary and secondary outcomes, but the numbers were too small to draw any meaningful inferences.

Impact of COVID-19

The COVID-19 pandemic resulted in the pilot trial being stopped in March 2020. Based on national responses to the pandemic, we proposed the following substantial protocol amendments to have the option to continue the trial:

- adding options for remote recruitment, including consent and baseline assessment
- expanding recruitment options by removing the exclusion criterion regarding initial accommodation and involving primary care teams as participation identification centres

- including questions related to COVID at assessment and follow-up
- pausing the group intervention while social distancing measures are in place
- adding an option for remote delivery of individual intervention
- offering 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 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, and 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 users found gender matching helpful. The lay therapists reported that participating in the PM+ intervention as an intervention lay therapist benefitted their own mental health owing to the PM+ lay therapists forming a cohesive group with a clear sense of purpose. They enjoyed working across different cultures but encountered some challenges in operating with different languages, and co-ordinating the study with their other roles.

Summary of findings against objectives

- The form and content of PM+ were successfully adapted to meet the needs of AS&Rs in the UK. Key findings from evidence synthesis and stakeholder engagement were integrated to provide relevant contextual modifications.
- The feasibility of the proposed training measures, including the involvement of refugees as lay therapists, was fully demonstrated.
- Preliminary data were gathered on the feasibility of proposed measures for recruiting distressed AS&Rs as study participants. Initial observations were that recruitment requires a considerable investment of energy and time and that it may be most effective when it NGOs are involved (as AS&Rs are more likely to have trust in these organisations).
- The feasibility of retaining lay therapists was demonstrated; despite considerable delays, by the end of the study six lay therapists were still actively engaged. There was preliminary evidence of the feasibility of retaining study participants at both the 3- and 6-month follow-up points.
- There was preliminary evidence (based on the assessment of eight individual PM+ sessions delivered by two lay therapists) of fidelity of intervention delivery.

- 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, as well as the conceptual nature of mental health questionnaires mental health questionnaires.
- The 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 AS&Rs in the UK.

We demonstrated that the form and content of PM+ can be adapted to meet the needs of AS&Rs, and that AS&Rs 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.

Trial registration

This trial is registered as ISRCTN15214107.

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