FULL/LONG TITLE OF THE STUDY

Routes to Wellness: Co-designing Peer Support for Refugees and Asylum Seekers

SHORT STUDY TITLE / ACRONYM

Routes to Wellness

PROTOCOL VERSION NUMBER AND DATE

Protocol V3, 18.07.2023

RESEARCH REFERENCE NUMBERS

IRAS Number:	**313046**
University of Plymouth FREIC number:	**3362**
FUNDERS Number:	**NIHR134589**

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Date:
.14/10/2022

Signature: 

.....

Name (please print): Sarah Jones

.....

Position:

Position: Research Governance Specialist and University of Plymouth Sponsor Representative

.....

Chief Investigator:

Date:14/10/2022

Signature:

.....

Name: (please print):

.....HELEN LLOYD.....

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KEY STUDY CONTACTS

Chief Investigator	Helen M Lloyd Helen.lloyd-1@plymouth.ac.uk 07967022965
Sponsor	Mrs Sarah C. Jones, University of Plymouth Level 2, Marine Building Drake Circus Plymouth PL4 8AA T: (0) 1752 588959 E: plymouth.sponsor@plymouth.ac.uk
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	National Institute for Health Research
Key Protocol Contributors	Helen Lloyd, Hoayda Darkal, Kristin Liabo, Debra Westlake, GARAS Adele Owen, Rachel Tribe, Sana, START Isaac Kelly and Si Parham, Celia Edwards.
Committees	PPI Group, local Impact Group and NIHR Steering Group

STUDY SUMMARY

Study Title	Forced to Flee. Co-designing a peer-led community approach to support the mental health of refugees
Internal ref. no. (or short title)	Forced to Flee
Study Design	Mixed methods; Experienced Based Co-design and Feasibility Test
Study Participants	Refugees & Asylum Seekers Health and social care professionals, staff from non-governmental organisations Peer support workers Managers and service leads
Planned Size of Sample (if applicable)	Approximate sample size n=120; qualitative sample size n=77, which includes n=15 people who will also complete quantitative outcome measurement in phase 3, bringing that total for quantitative measurement n=30, co-design workshops n=28.
Follow up duration (if applicable)	Phase 3 feasibility test: 3months and 8/9 months
Planned Study Period	September 2022 – Nov 2024
Research Question/Aim(s)	The principal objective of this study is to design and test a peer-support model for refugees. Research questions:

	How do refugees conceptualise, express, and experience mental health issues and how does this relate to the other difficulties they experience (physical, social, occupational, residential, cultural etc.)? Is a co-designed PSW model acceptable to refugees, PSWs themselves and services with whom they work? Do PSWs themselves benefit from delivering the model? What are these benefits and how should we measure them? Are there any disbenefits or unanticipated outcomes associated with the PSW model for refugees and/or PSWs? What are the barriers and facilitators to the implementation of the co-designed model? Is it possible to detect improvements in mental health associated with the co-designed PSW model? If so, what is the best way to capture or measure them?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
National Institute for Health Research (NIHR)	All research costs at 80%FEC
Do we put CRN here?	Excess treatment costs

ROLE OF STUDY SPONSOR AND FUNDER

This protocol presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Advisory Group

An advisory group of 8 people will convene a maximum of four times throughout the study's duration. The role of this group will be to offer expertise in specific areas related to this research and to provide guidance, when needed, on how best to take the research forward.

Chair: Associate Professor Sabi Redwood, Deputy Director of ARC West. Bristol University

Members: Professor Chris Dowrick, Professor of Primary Medical Care, University of Liverpool, Dr Loubaba Mamluk, Senior Research Associate, ARC West, Ms Angelina Jalonen, Head of Therapeutic Services, Refugee Council, Ms Bronwyn Prosser, Policy Officer, SouthWest Councils, Mr Erfan Alaei, Expert by experience.

Local Impact Group

A local impact group has been developed to advise on the development of the peer support worker service and evaluation to make sure that the knowledge generated from this work is useful for service commissioning, planning and delivery. We expect this group to meet about 3 times per year.

Members: Si Parham; Colebrook SW, Avril Bellinger; (START), Ian Veale; Livewell, Miriam Kingoo; Red Cross

Kate Lattimore; Plymouth City, Jessica Dann; Community Connections (Asylum Seekers and Refugees), Adele Owen; Gloucester VCS, Philippa Chapman (GP), Darin Halifax : VCS lead Devon STP, Alex Vessis; Devon and Cornwall Refugee Service, Kiven Emmanuel; Plymouth Hope.

Patient & Public Involvement Group

A PPI activities are interwoven in the design of this study through the co-design activities. However in addition to these activities experts by experience will also meet with the PPI lead (Liabo) in small focused meetings and larger group meetings, the latter of which we expect will convene about three times throughout the duration of the study and consult on:

1) Design of the research
2) Management of the research (service-user member on study advisory group)
3) Developing participant information resources
4) Undertaking/analysing the research (e.g. service user facilitators)
5) Contributing to the reporting of the study report
6) Dissemination of research findings

PROTOCOL CONTRIBUTORS

Lead researcher: CI Lloyd, all Co-applicants and our PPI group.

Patient and public involvement group

KEY WORDS: Refugee, Peer Support, Experience Based Co-Design, Mental Health, Co-production

Terms used in this Protocol:

When we refer to the project team or 'we' this means all co-applicants and service user representatives. We use the term 'refugee' to mean people who have been granted settled status, those allowed entry within a refugee support scheme, and those arriving to the UK seeking asylum (Article 1, 1951 UN convention). When we describe the PSW approach, we use 'refugee' to mean the person who receives support but of course the PSW will also have a refugee background.

The term 'mental health' in this proposal is used as a broad term to reflect the common mental disorders experienced by refugees e.g., anxiety, depression, and posttraumatic stress disorder, as well as mental distress without a clinical diagnosis. We define mental health from an embodied psychosocial and cultural perspective, e.g. that individuals will experience mental distress in a variety of emotional, cognitive, and physical ways, and that understandings and expressions of these are socially and culturally patterned. We also view mental health and wellness on a continuum. We anticipate that our Experienced-Based Co-Design (EBCD) work will produce a variety of idioms of distress that are shaped by refugees and understood by them, and the research team, PSWs and the services supporting them. We use the terms involvement, co-production and co-design to describe differing forms of equitable collaborative work between service users, providers and university researchers. This approach embodies the ethics of equity that is at the heart of our work.

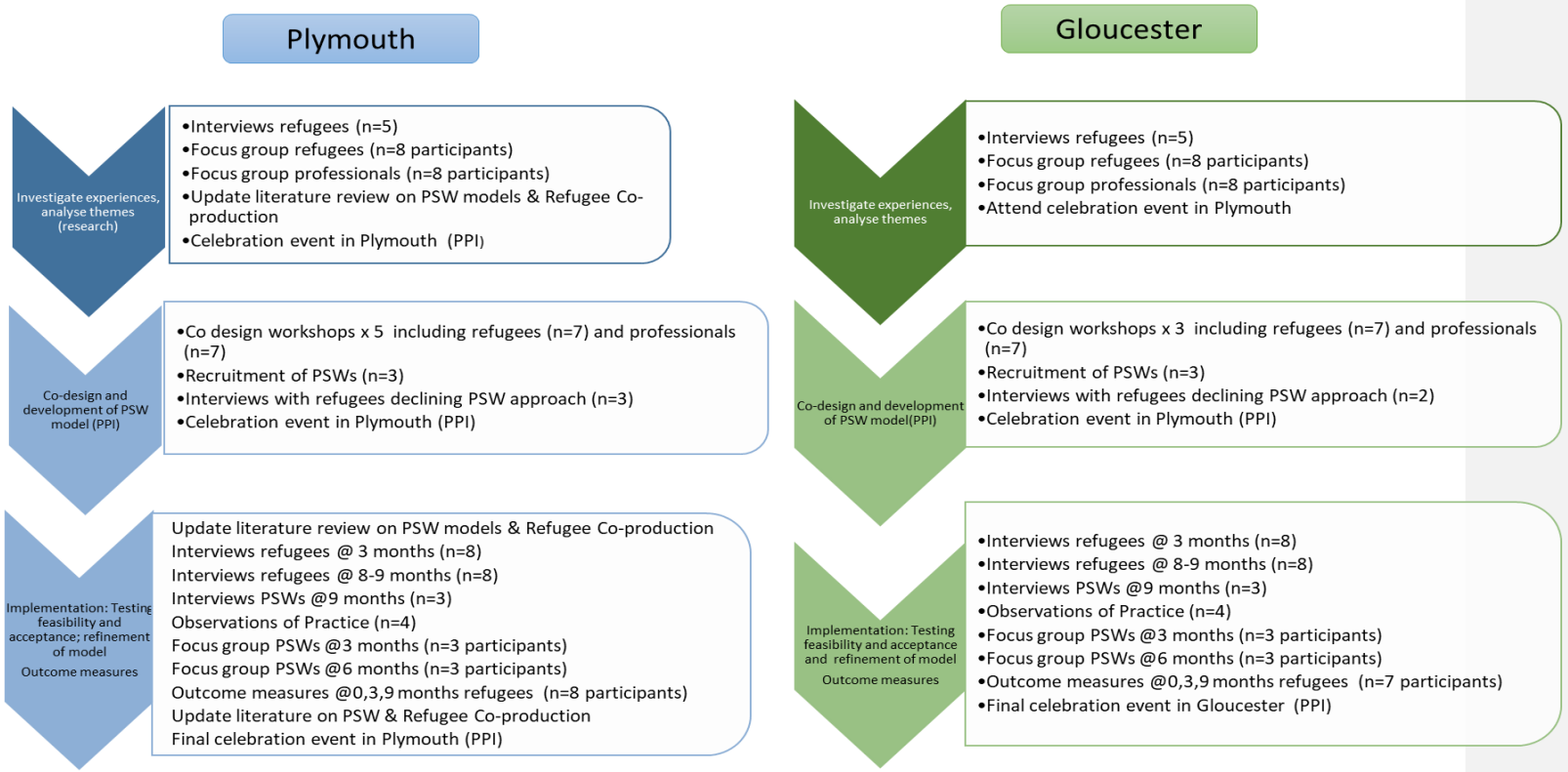
The term 'model' is used in this proposal to refer to the PSW intervention (approach, training, delivery manual, refugee facing materials) and a term widely understood and favoured by our key stakeholders within the community and across this team.

The term ‘service user experience’ throughout this proposal and ‘people’s personal account of having a health condition/using services’, refers to ‘lived experience’ which will be collected using qualitative methods.

Study flowchart

Activities	Feb, Mar, April 2022 Months -3	May, June, July 2022 Months 1-3	Aug, Sep, Oct 2022 Months 4-6	Nov, Dec 2022 Months 7-8	Jan, Feb, March, Apr 2023 Months 9-12	May 2023 Month 13	Jun, Jul, Aug 2023 Months 14-16	Sep, Oct 2023 Months 17-18	Nov, Dec 2023 Months 19,20	Jan, Feb, Mar 2024 Months 21-23	Apr, May, Jun 2024 Months 24-26	Jul, Aug, Sep,Oct 2024 Months 27-30
Ethics, governance, permissions												
EBCD: Investigate mental health and service experiences												
Local & national meetings												
Interviews with refugees (n=7-10)												
Observations of current practice (n-5-7)												
Transcription & analysis of data												
Focus Groups with professionals (x2)												
Focus Groups with refugees (x2)												
Transcription and analysis of data												
Update review and synthesise data for workshops												
Celebration event												
EBCD: Develop the Intervention												
Co-design workshop: programme theory x1												
Co-design workshop: PSW model x3												
Co-design workshop: PSW manual x2												
Co-design workshop: refugee materials x1												
Co-design workshop: outcomes/measures x1												
Finalise model, manual, materials												
Celebration event												
Recruit and Train PSWs for feasibility test												
Feasibility Test & Evaluation												
Test Run PSWs working with refugees												
PSW focus groups & interviews												
Refugee interviews & update review												
Transcription and analysis of data												
Co-design workshop: update PT												
Co-design workshop: update Model, training												
Co-design workshop: update manual/materials												
Refine all materials												
Write P1 report												
Write P2 report												
Write P3 report												
Final Celebration Event												

Flow chart of research and PPI/Co-design activities by site



STUDY PROTOCOL

Forced to Flee. Co-designing a peer-led community approach to support the mental health of refugees.

1 BACKGROUND AND RATIONALE

Because of displacement and resettlement, refugee and asylum seekers experience higher levels of distress (Fazel *et al., 2005*) and mental illness (Steel *et al.*, 2009; Jayaweera, 2014; Graetz *et al.*, 2017; Steele *et al.*, 2018), most commonly anxiety, depression, trauma and functional impairment (Close *et al.*, 2016; Priebe *et al.*, 2016), when compared with other migrant and majority groups (Priebe *et al.*, 2016). Poor socioeconomic conditions, acculturation stressors, discrimination, and economic uncertainty (Priebe *et al.*, 2016; George *et al.*, 2015) exacerbate mental health problems for refugees. Accessing health care can be challenging due to a lack of shared language and understanding in relation to mental health (Resera et al., 2015; Tribe & Thompson, 2017). In addition there is limited training for health providers in culturally sensitive trauma care, which leads to misunderstanding and misdiagnosis for those who manage to access services (Thomson *et al.*, 2015). Many refugees are isolated from their cultural or religious groups, resulting in feelings of alienation, thus restricting opportunities for healing and personal growth. The coalescence of these factors create significant barriers for refugees attempting to access services (Priebe *et al.*, 2016; van der Boor & White, 2020), creating substantial levels of unmet need (Bradby *et al.*, 2015).

Forced migration also creates losses across all multiple life domains for refugees. A profound disruption to sense of self is often caused through multiple losses of family, friends, home, hobbies, and employment. These combine with arrival experiences to create post migration stress, a lack of autonomy and a sense of powerlessness in even the most resilient individuals. Approaches to support that enhance social capital, self-efficacy and psychological well-being through social support, cognitive strategies, education, and training and through employment and economic activities (Posselt *et al.*, 2018) have the potential to improve refugee experiences and outcomes. Peer-support workers have been found to reduce hospitalisations (Chinman *et al.*, 2008) and improve social functioning (Yanos *et al.*, 2001). Delivering psychosocial support in the community using peer-support workers provides an accessible route to non-stigmatising mental health support for refugees (Hoeft *et al.*, 2018).

Evidence suggests that refugees desire support in the community to build resilience, improve their health and promote social and economic development (Arnetz et al., 2013; Misra *et al.*, 2006; O'Neill, 2018). Community settings also offer a route to referral and signposting activities to improve access, prevent escalation, and improve mental health outcomes (Brainard *et al.*, 2017). Peer-support interventions bring people together with similar experiences, with the potential to bridge the social and service gap between health professionals and patients (Coleman & Campbell, 2009). This promotes mutual respect and trust for information sharing and health promotion.

A systematic review of these types of approaches has shown them to be effective in low and middle-income countries (van Ginneken et al., 2013). Small-scale evaluations of such schemes report positive user experience, but also challenges in finding the right approach (Misra *et al.*, 2006; Oddi *et al*, 2014; Balaam *et al.*, 2015; Jackson-Blott *et al*, 2015; Fazel *et al*, 2016; King & Said, 2019); issues that are common to the implementation of peer-support models in mental health (Ibrahim *et al.*, 2020). There are a number of factors that need to be investigated in relation to these interventions in high-income countries such as the UK. These range from how to help peer-support workers in their role, their self-perceived competence, acceptance of the workforce by partner organisations, and sustainability (Padmanathan & De Silva, 2013).

Contextual factors important for the co-production of health in refugees have been identified in a recent scoping review (Radl-Karimi *et al.*, 2020). These were: co-production being prioritised by the organisation providing the support, a safe environment that fosters trust, using a language that the refugee understands, showing respect

for the refugee's own knowledge and priorities, flexibility in response (which they call improvising with knowledge and courage) and engagement in self-reflection (by provider and refugee) (Radl-Karimi *et al*., 2020).. These principles for the positive co-production of health are echoed in our study design and proposed activities within the model.

2 THEORETICAL FRAMEWORK

There is now widespread recognition that the development and implementation of healthcare inventions are enhanced by applying theory (Craig *et al.* 2008). Despite this, many interventions fail to positively impact the delivery of care (Chalmers *et al.* 2014), often due to the lack of a sound theoretical underpinning (Michie *et al.* 2005). This study is underpinned by the principles of realism and pragmatism [68]. This blended lens allows for the exploration of the generative mechanisms that exist to cause given outcomes. It acknowledges that the exploration and identification of such mechanisms is achieved through a process of data generation filtered through our subjective perceptions and experiences. Pragmatism recognises the need to tackle pressing social and health problems using the most appropriate methods to achieve change. Our approach also reflects an emancipatory epistemology typical of Action Research [69], which attempts to practice an ethic of equity and equality to safeguard and value the views and experiences of all those involved as equal collaborators. The research project will be 'done with' and not 'done to' people and will strive to create mutual benefits for all involved.

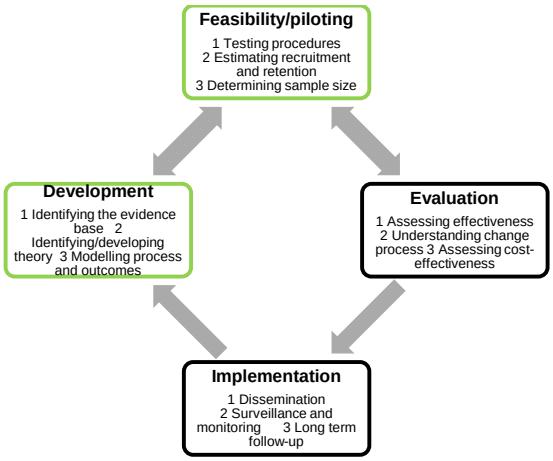
We propose to use a simplified form of Realist analytical methods to help us develop our programme theory of how the PSW model works to improve outcomes, for whom it works, and to identify what core conditions have the potential to maximise the successful delivery and implementation of the model. This is because the PSW model involves a number in interacting and complex strands e.g. PSW training, supervision, mentoring, refugee uptake, and PSW and refugee interaction and signposting. In addition to this the heterogeneous nature of refugee population, and the involvement of multiple service providers further necessitate a systematic and thorough analysis of who benefits and how, and what conditions support this. This method provides an evidenced-based and theory driven PT whilst also using the lived experiences of co-design participants. Workshops across during months 14-18 and 26-28 will provide the forums for developing IF-Then statements using our data and the lived experience of co-design participants. We have added additional text at page 13 of the detailed project plan to describe this process in more detail.

3.1 The MRC Framework

The MRC Framework (MRC 2000, 2008) guides researchers in recognising and adopting appropriate methods when developing complex interventions (Craig *et al.* 2008). Developing a feasible and acceptable intervention or model with people with lived experience takes time and resources; particularly when the phenomena under investigation is not well understood (MRC 2008). To build an ecologically valid peer support model which is acceptable to refugees and service providers the focus of the current study is the developmental stage of the model and the feasibility piloting phase of the MRC Framework (Figure 1). The feasibility and acceptability test of the peer support model will be performed in Plymouth and Gloucester.

Figure 1

MRC Framework (green indicates the elements to be conducted in this study)



3.2 EBCD and the MRC Framework

Health and care interventions exist within dynamic systems (Greenhalgh *et al.* 2004) with multiple stakeholders across multiple interfaces. Understanding the experiences, motivation and behaviour of key stakeholders within care settings is crucial to the development of interventions and their successful implementation (Murray *et al.* 2010). In recognition of this EBCD was considered the most suitable method to develop the peer support worker model, since it prioritises the experiences of service-users and providers. EBCD is an approach to developing services and improving health and care services by blending participatory approaches with narratives, user experience and design (Jayaweera, 2014, Greenhalgh *et al.*, 2004). Through a process of 'co-design' multiple stakeholders (public, professionals, commissioners) are brought together in an iterative process to reflect on their needs and experiences of a service, to identify areas of improvement and to develop and implement changes. These achievements will be reflected on at local celebration events. A full EBCD process consists of sequential phases of narrative based data collection and co-design (see fig. 1; Pi). Once we have developed the PSW model we will then test its feasibility and acceptability in two study sites using qualitative methods.

3 RESEARCH QUESTION/AIM(S)

3.1 Research questions

1) How do refugees conceptualise, express, and experience mental health issues and how does this relate to the other difficulties they experience (physical, social, occupational, residential, cultural etc.)?
2) Is a co-designed PSW model acceptable to refugees, PSWs themselves and services with whom they work?

3) Do PSWs themselves benefit from delivering the model? What are these benefits and how should we measure them?
4) Are there any disbenefits or unanticipated outcomes associated with the PSW model for refugees and/or PSWs?
5) What are the barriers and facilitators to the implementation of the co-designed model?
6) Is it possible to detect improvements in mental health associated with the co-designed PSW model? If so, what is the best way to capture or measure them?

3.2 Aims

This study aims to explore refugee and provider experiences and use these to co-design a PSW model to support the mental health of refugees in Plymouth and Gloucester. We will work with refugees and key stakeholders to understand the benefits and challenges of implementing the model over the course of this project using qualitative methods.

Objectives:

Use EBCD to:

a) Develop a transcultural understanding of the varied ways in which refugees conceptualise, experience and articulate mental health issues and explore how this relates to their physical, social health and overall wellbeing and their experiences with services

b) Develop key components of the peer-support model (content & mechanisms of delivery) using touchpoints from a), and identify what outcomes are relevant to measure

c) Identify suitable media to communicate how refugees conceptualise and articulate their mental health experiences and cultural and psychosocial needs

d) Refine our programme theory of how the model works

e) Agree how to incorporate 1c into the PSW manual, materials and training package

Run a preliminary acceptability and feasibility test of the model in Plymouth and Gloucester to identify:

a) The strengths and weaknesses in the model

b) The practicalities and optimal processes for the recruitment and retention of refugees and PSWs and barriers and facilitators to engagement

c) How to optimise and enhance delivery of the model

d) The parameters for large scale implementation and appropriate evaluation methods

e) How the model could be transferred to other settings

3.3 Outcomes: Success criteria and barriers to proposed work

Our success will be judged on the extent to which we are able to meaningfully engage with refugees and recruit them to the research and development activities. We will use feedback forms throughout the study to gauge how we are doing and aim to keep an open dialogue within the research team and the local reference group. Working with local commissioners will help link this research to future service provision for refugees in Plymouth and Gloucester. We will work to the following key outcomes:

- Acceptability of the co-designed PSW model to refugees and PSWs
- Successful feasibility test of the model in Plymouth and Gloucester
- Benefits for PSWs as defined by them through qualitative data collection
- The identification of an acceptable core outcome set for use in a future implementation and effectiveness trial
- A PSW model that is acceptable to local commissioners.
- Refugees and PSWs report benefits in mental health and social improvements by engaging with the model

We know from other studies that barriers to the successful completion of the project may include insufficient recruitment and retention of PSWs due to changing status, resettlement or other employment, or failure to reach out to people in the refugee community. The co-production that built the funded proposal of this research anchored our research in the community, our local impact and engagement groups should mitigate this.

The refugee population are known to be subject to digital inequalities, particularly highlighted by the move to virtual service contacts under COVID. Similarly, there might be lack of engagement and take-up of the intervention by refugees. Again, the close collaboration between co-applicant partner organisations will instil trust in the approach within the refugee community. We have made provision for PSWs to have digital technology that will allow them to contact service users virtually and are working with partner organisations to increase access to hardware (smart phones) for refugees.

Participants may be reluctant to complete outcome measures for a variety of reasons including trust, language difficulties and low reading ability. To counter this we have budgeted for interpreters and costed for the translation of written material. Core members of the co-applicant team have worked together on building this application for the last two years, which strengthens our ability to address challenges to the work. We will establish routines for research practices to ensure that we maximise participation and will be led by our expert advisors and NGO partners to achieve optimum data collection. Incentivising this process will help counter this issue along with the use of and peer support workers.

4 STUDY DESIGN/METHODS

4.1 Overview of the study

The study will be conducted in three phases;

- **Phase 1 - EBCD: Investigate the Mental Health Experiences and Needs of Refugees & Service Providers**
- **Phase 2: EBCD process to Design the PSW Model**
- **Phase 3: A Feasibility and Acceptability Test of the PSW approach**

4.2 Phase 1 - EBCD: Investigate the Mental Health Experiences and Needs of Refugees & Service Providers (Months 4-12): Aims, Data Collection & Analysis

Aims:

- Explore the lived experience of refugees and the ways in which they experience mental health and related issues, their levels of need, their experiences of seeking/gaining help from existing services
- Explore refugees preferences and attitudes towards the proposed peer-support model. We will specifically explore the problems they face in accessing and receiving appropriate support.
- Explore the experiences of staff in Plymouth and Gloucester to understand the issues that they face in delivering services to refugees, where they believe there are gaps in current provision, what can be done to improve this, and how the PSW model will solve this issue.

Data collection:

- **Refugee interviews:** Refugees will share their 'lived' experiences directly by taking part in a one-to-one narrative interview, this will maximise the participation of those who might feel stigmatised talking about mental health in a group setting.

- **Focus groups with refugees:** will be used to maximise representation from refugees who may feel more comfortable talking with people who are similar to them in terms of ethnicity or religious group. It may be necessary to provide women and men only focus groups if mixed groups present a barrier to participation.

- **Focus Groups with Professionals:** from service provider organisations will be conducted to garner their experiences of working with refugees. Focus groups will help us garner important insights from the perspectives of professionals and provide touchpoint data. Touchpoint data from observations, interviews and focus groups will be used as the basis of discussion in the co-design workshops in the following phase to develop the PSW model and be used to develop our programme theory of how the model will work.

  Observations of refugee & PSW interactions: An ethnographic approach (Atkinson & Hammersley, 2007) will be used to observe refugee and PSW interactions during the pilot test. Observations will enhance our understanding of these interactions, and how they are influenced by the setting and context. They will also provide insight into the barriers and facilitators to active engagement and areas of practice that could be enhanced and improved. Field notes generated from the observations will be analysed to help us to identify emotional touchpoints (Bate & Roberts, 2007) and expressions of mental distress. Observational guides will be drafted by the researchers and reviewed by PWs and refugees
- **Update Literature Review:** on PSW models and refugee co-production. This will ensure that the latest evidence is integrated into our programme theory and the PSW development process in the following phase. Searches will be initiated, and papers will be screened and appraised based on our existing review protocol and screening tool aimed to identify a) PSW evaluations to improve mental health in adult refugees and b) evaluations of co-production research with adult refugees internationally. The parent terms for these searches were:
  - Peer-support evaluations:
    - ((TITLE (refugee* OR (asylum W/2 seek*) OR (displaced W/2 (people OR persons)) OR (forced W/2 (flee OR migrat*)))) OR (KEY (refugee* OR (asylum W/2 seek*) OR (displaced W/2 (people OR persons)) OR (forced W/2 (flee OR migrat*))))) AND (TITLE (advocacy OR advocate* OR peer* OR mentor* OR (

Commented [HML1]: We have found it difficult to initiate observations due to the precarious situation of refugees. At a practical level it felt unethical to this and whilst we tried to find non invasive and non intrusive ways of doing this both providers and refugees felt uneasy about the process.
We raised this with our steering committee who advised us that we should drop the observations on this basis agreeing that there was potential to risk breaking trust and distressing people.

lay W/2 therap**)) OR KEY (advocacy OR advocate* OR peer* OR mentor* OR (lay W/2 therap**))) AND PUBYEAR > 2000

- Co-production research evaluations:
  - (((TITLE (refugee* OR (asylum W/2 seek*) OR (displaced W/2 (people OR persons)) OR (forced W/2 (flee OR migrat*)))) OR (KEY (refugee* OR (asylum W/2 seek*) OR (displaced W/2 (people OR persons)) OR (forced W/2 (flee OR migrat*)))))) AND (TITLE-ABS-KEY (coproduc* OR co-produc* OR co-design* OR codesign* OR co-creat* OR cocreat* OR ((participatory OR experience* OR co-research OR evidence* OR collaborative OR human-centred OR people-centred OR inclusive OR practice-led OR practice-based OR interactive OR open OR user-cent*) W/2 design*))) AND PUBYEAR > 2000

Analysis: EBCD Analysis of Experiential Data (Months 4-12)

All interviews and focus groups will be recorded and transcribed verbatim and double checked for accuracy with audio recording. Transcripts will be deidentified to protect the anonymity of participants The overall approach to data analysis will be guided by a Thematic Framework approach (Smith & Firth, 2011). This will allow the charting of themes in relation to how mental health is conceptualised and expressed and the problems refugees face accessing help. This will allow the identification of similarities and differences in experience from the varied subjective perspectives of research participants. Interviews, focus group transcripts and field notes will be analysed to identify positive and negative touchpoints. If refugees are willing, we will video or audio record some of the interviews to create a trigger film which depicts emotional touchpoints. This could then be used in the co-design workshops, the training and by provider organisations who will support the delivery of the PSW model. Touchpoints will be identified by the research team to identify access issues/barriers to service provision, descriptions of mental health and health related experiences judged to trigger negative or positive emotions. A representative subset of transcriptions will be anonymised and presented to our project team (Locock *et al*., 2019). The group will read this data individually and in pairs, assessing the examples for positive, negative or indifferent emotional triggers. The researchers will then use identified 'touchpoints' from the group and identify further and recurring themes, thereby refining our understanding of the important 'touchpoints', including variations across cultures. The findings will also characterise how services currently support refugees and how this can be improved in the adapted model. The synthesised findings from this work will be used in the co-design workshops to shape the content of the training for the new model which will be in the subject of the acceptability and feasibility test.

Our refugee co-applicant and refugee PPI contributors will enhance the trustworthiness and credibility of our analytical processes (Morse *et al*., 2002). However, we will also ensure trustworthiness of the data and the findings by prolonged engagement with the data, researcher triangulation, data triangulation, consistent memoing for reflexivity, an audit trial of code generation and detailed notes re the development of hierarchies and concepts, reference back to the raw data and respondent validation where appropriate.

Celebration Event:
Study progress and findings will be shared at the celebratory events. They will also be advertised at Livewell, START and GARAS in the form of leaflets in the main languages used by service users. All participants will be asked if they would like to receive information about the project by email, post or text alert and study updates will be shared to them in conjunction with the celebratory events. Study progress will also be shared on a study website using short videos and a range of other material translated into the main languages used by service users.

4.3 Phase 2: EBCD Co-design the PSW Model: Aims, Design Activities, Peer Support Worker Recruitment and Training (Months 13-19)

Aims:

- Co-design the PSW model, manual, training, and refugee facing materials by blending our synthesised qualitative touch point data, with updated evidence from our literature review with user-based co-design (see flow chart on page ii)
- Refine and develop our programme theory (PT)
- Jointly define and agree our process and outcome measures

Data collection:

Data will be collected in the form of reflective notes, minutes, key decisions, and ranking and summary data from the outcome and measurement workshop.

Key outputs:

- The structure, form and content of the PSW model detailed in a PSW delivery manual
- PSW training materials (manual, powerpoint etc..)
- Refugee facing materials (translated leaflets etc..)
- An UpToDate Programme Theory
- A list of prioritised process and outcome measures

EBCD Groups: The co-design workshops will consist of a maximum of 20 individuals including researchers, refugees, and professionals from service providers. To develop the PSW model (incl. programme theory, training, delivery manual and refugee materials) and define and determine outcomes and outcome measurements we will convene 8 co-design workshops guided by the EBCD toolkit (Point of Care Foundation 2018).

Workshop 1: Aim: Feedback the results from the literature and fieldwork (observations, interviews, focus groups, trigger film and touchpoint data). This will include an overview of the various ways in which participants expressed distress, mental or physical health issues, their needs and experiences in accessing services. Through this process it is possible that additional touchpoints could be identified. It will also include an overview from the literature on refugee experiences in accessing services, how services are currently delivered and evaluated and if and how they work to improve refugee outcomes. Depending on the composition of the groups we will prepare suitable mediums of communication including but not limited to images, words and creative exercises to communicate key findings and facilitate feedback from group members (Brown & Choi,2018). The discussions and key points from this workshop will be recorded, analysed and synthesised.

Workshops 2 & 3: Aims: reflect on the findings from workshop 1 in small groups and further draw on the experiences of our co-design members to reflect on proposed core ingredients of the PSW model e.g. narrative, goal setting and support to access services to achieve goals. Breaking again into groups to jointly reflect and discuss the proposed PSW model in relation to our fieldwork data and the existing literature. This will help consider and define how PSWs should approach the process of engagement with refugees, narrative construction and goal setting. Our engagement work suggests that the following emergent characteristics could be covered in this workshop:

- How to screen for risk (e.g., using Livewell tools or identifying others), how to manage risk, self-care, and how refugees should best engage with services
- How to engage in a narrative dialogue and identify personal health goals

- How to consider both semantic and somatic expressions used to communicate distress across refugee groups (how do these converge and diverge)
- The interpersonal approach, preferences for contact for PSW and refugee meetings
- The impact of COVID situations i.e., if social distancing measures, remote interactions etc.
- Duration and frequency of contact for PSWs and refugees (e.g., to balance need with support)

Once we have developed descriptions of the core aspects of the PSW model, another set of co-design workshops will take place.

Workshop 4: Aim: Design the training and on-going support of PSWs, this will include:

- Training; content e.g. narrative, strengths, trauma sensitive approaches
- Training methods; e.g. cartoons, podcasts, videos, stimulated interactional dialogues/role play, apps, group work, and didactic content (over 5 days), and delivery preferences e.g., mental health trainers from Livewell, the researchers and co-applicant team etc.,
- On-going supervision & mentoring; frequency, duration, approach, and delivery preferences

Workshop 5: Aim: Design the delivery of the PSW model and supporting materials

- Model & manual; how the model will be delivered (e.g., audio, visual, paper based, web platform or paper based) and key information to included (e.g., Peer Support Worker Competence Framework for Mental Health (UCL, 2020), and the extent to which it can be manualised and the right approach for this.

Workshop 6: Aim: Design Refugee Facing Materials that support the delivery of the approach

- This workshop is designed to focus specifically on the materials to be developed to support refugees engaging with a PSW. It is likely that there will be some overlap with materials developed for workshop 5 but for use during contact with the PSW, but this workshop will also identify what other materials refugees might find useful when not meeting with a PSW.

Workshop 7: Aim: Refine Programme Theory

- This workshop will update and interrogate our PSW programme theory. This will align our PT with the experiences of our co-design group, the most up-to-date literature, and findings from the fieldwork. We will present our existing PT to the main group and then break into smaller groups to elicit 'If Then' causal statements about how the PSW might work to improve outcomes for refugees. We may employ images and pictorial representation to make the discussions more inclusive. Following a discussion and prioritisation round, where we jointly agree the most important IF-Then statements, we will identify the contexts that are likely to produce these outcomes. The output from this workshop will be a consolidated set of IF-Then statements (micro theories) that have been informed and scrutinised against the lived experiences of our group. Eliciting IF-Then statements is a common method in Realist theory building. It facilitates the involvement of key stakeholders in the development of micro theories that contribute to an overall programme theory grounded in a shared and agreed reality that is sensitive to context.
    - An example of an IF-THEN statement might be "If PSWs and refugees share a common arabic language THEN their engagement will be more productive and enhance the potential to jointly identify issues of concern for the refugees".

workshop 8: Aim: Identify and Scrutinise Outcomes Measurement Tools

- This workshop will use our literature review and our own data to present measures that map to the important outcomes described for PSW models. This could include measures of personal growth, mental health and social network and wellbeing etc. We will present the group with an overview of our previous PT and top line findings from updated literature review (conducted by month 12). We will then break into smaller groups to consider potential outcomes and present a range of options for measurement. We will ensure that breakout groups are representative of all key stakeholders and then ask them to select the most favoured measures ranking them in order of relevance and acceptability (language, comprehension and ease of completion). The highest scoring and most acceptable measures will be incorporated into our acceptability and feasibility test (see below).

Peer Support Worker Recruitment and Training:

Six refugees will be trained as PSWs during month 19 to deliver the intervention in Gloucester (n=3) and Plymouth (n=3) during our feasibility and acceptability trial in our next phase. All PSWs will have a refugee background.

- **Recruitment:** PSWs will be recruited for their posts using procedures and policies currently employed at START, Livewell and GARAS. Recruitment posters and information sheets will be displayed at START, Livewell, GARAs and other statutory and non-statutory settings supporting refugees in Plymouth, and in Gloucester. Researchers will attend scheduled events and meetings at the partner organisations to explain the project and role. We will also make refugees aware of these posts during the EBCD phase.
- **Selection:** Inclusion/Exclusion Criteria to Ensure That Certain Groups are not Excluded without Justification:
    - For PSWs: adults (aged 18 and over), proficient English, settled status in the UK after arriving as a refugee or asylum seeker, an interest in mental health and peer-support. Those who fulfil the criteria for the post via a shortlisting exercise will be invited for an interview by the project team and asked to undertake a short task that demonstrates their language proficiencies and interpersonal skills. This will be to ensure that anyone with an interest in the role can apply, are aware of the nature of the role, and that the roles are filled by people with the relevant experience, interpersonal skills and approach. Willingness to be interviewed by the researchers and peer-researchers will be a requirement of this role.
- **Training:** This will be delivered as per the design laid down by the EBCD process described above.

Making the film or audio compilation

If participants are willing, a 30-minute film using segments from service-user interviews will be created. The film will show "touch points" i.e. crucial moments that have either a positive or negative influence on a person's experience of a service or event (Bate & Robert 2007), in this case, refugee experiences of interactions with professionals. The aim of the film is threefold:

1) Ensure the service-user voice is heard within the co-design process,
2) Enable staff to see a true picture of how service-users experience engagement within their service,
3) Stimulate discussion between staff and service-users at co-design events to develop the potential improvements that can be made to engagement.

The film will be made in the following way:

1) Touch points will be identified by editing snippets from each participants' filmed interview and saved on a digital platform which is password protected. The School of Psychology have excellent audio visual labs for this purpose and routinely edit audio visual material supported by a technical support team.
2) Participants will view the video or audio if preferred of their touch points with the lead researcher at a mutually convenient time and place. Participants will be asked to sign a form asking for their consent and release of the footage for use in the 30-minute trigger film and for future educational purposes
3) Participants will be given a short survey that asks them to rank the three most important touch points based on their personal experiences, to be included in the 30-minute film.
4) Once the findings have been agreed, the touch point films will be edited into a 30-minute film by the research team with support from the School of Psychology's technical team.

4.4 Phase 3: A Feasibility and Acceptability Test of the PSW approach & Refine the PT: Aims, Intervention Description and Data Collection (months 20-30)

Aims:

- To test the acceptability and feasibility of implementing the PSW model
- Refine the PT
- Describe Impact
- Assess Appropriate Outcome Measurement

Design*:*

We will test the acceptability and feasibility of the PSW model in Plymouth and Gloucester over 9 months and evaluate it using focus groups and interviews in a single group pre-post-test design. In line with NIHR guidance we will investigate known uncertainties such as:

- Acceptability of the approach to the users
- Adherence to the approach
- Methods to ensure representative recruitment and engagement
- The ethics and suitability of design for a future wide scale evaluation study
- The choice of primary outcomes and their characteristics for inclusion in a co-designed evaluation framework
- The choice of an adequate comparator, if acceptable
- Follow-up rates, response rates to questionnaires, adherence etc.
- The time needed to collect, clean and analyse data
- Practicality of delivering the approach in the proposed settings
- Variation in use or delivery of the approach in each setting
- The likelihood/willingness of other geographical regions adopting and testing the approach

We will also test the process and outcome measures identified by our co-design group.

Methods: Trial Procedures & Peer Support Worker Approach (Intervention Description):

PSW and refugee first contact:

The PSW and the refugee will arrange to meet at a mutually convenient time and place that is suitable to maintain confidentiality and ease of communication (START or GARAS). It is expected that during this first meeting the PSW and the refugee will agree the expectations for their engagement. After careful clarification regarding the terms of engagement the PSW will initiate a narrative dialogue using active listening and a trauma sensitive compassionate style to understand what matters to the person in terms of their immediate concerns. Refugees will be provided with an opportunity to talk about what it means to them to live well, what they believe to be wrong with them, and what might be shaping their experiences. The acceptability of this and the way in which the dialogue is approached will be co-designed and defined in EBCD workshops along with the best way in which to jointly identify short and medium-term health and social goals.

This approach is core to Person Centred Care (PCC) and because it relies on the person's individual account and what they find challenging it has a culturally universal appeal (Gwozdziewycz & Mehl-Madrona, 2013). The PSW approach blends a focus on narrative with support to access services. This carefully attuned approach to interaction will ensure that it is not trauma inducing.

Within our PSW model, we expect that an emphasis will also be placed on jointly identifying the refugee's resources and skills (strengths) to build resilience, prevent the escalation of distress and increase self-knowledge. The PSW will then identify services and activities that could help deal with the person's immediate concerns, but also those which might help to achieve medium-term goals. This could be access to a range of medical and non-medical services, and activities to support their mental health in relation to identified goals.

PSWs will pay particular attention to how individuals understand and express their distress or problems, and will support the person's own understanding of how their problems are affecting them in bio-psychosocial way or in a way in which is personally meaningful to the refugee. PSWs will help refugees to express themselves when interacting with other services, whether by help of interpreters or in English. This will be achieved during the dialogue between PSW and the refugee. PSWs will record a brief synopsis of the outcomes of their interactions with refugees. We expect this will include a brief narrative summary, a list of identified short and long-term goals, agreed actions to address them, and contact and signposting information. The documentation will be recorded on a form and digitalised via a mobile device and provided to refugees in their own language with equivalent terms in English. Again, the parameters around how all the above activities are achieved, the acceptability of them, and possible alternatives will be decided and designed in line with the EBCD process. The process will also develop a sound ethical framework for practice. The above outline is simply to illustrate how the model might operate based on our existing work, but we acknowledge this may well change over the course of the project.

PSW Follow-ups:

Telephone follow-up and face to face meetings will be provided to explore if refugees have accessed appropriate services, where this has not been possible further action will be taken to support them. PSWs will actively follow-up if refugees have begun to meet their goals and help them develop new ones should this be appropriate. If there are barriers or problems in achieving goals PSWs will help refugees problem solve and support them to access services and support.

PSW Contact Frequency:

PSWs will have up to 19 hours of face-to-face contact time (approx. 2 hours per month) with each refugee to work in a flexible manner during the acceptability and feasibility test. We will assess if this is sufficient at the end of the acceptability test. Refugees and PSWs will also be provided with a contract mobile phone to facilitate

contact with their PSW, their family, other refugees, services, and community activities and to maintain contact with each other. This will form a mechanism both for social support and social capital, and as a method to facilitate access to services and activities.

Analysis: Analysis of Qualitative Data and Measurement Data (Months 20-30)
All interviews and focus groups will be recorded and transcribed verbatim and double checked for accuracy with audio recording. Transcripts will be deidentified to protect the anonymity of participants. The overall approach to data analysis will be guided by a Thematic Framework approach (Smith & Firth, 2011). This will allow the charting of themes in relation to if and how the PSW model has helped refugees and the acceptability of the peer-support model. Delivery issues will also be explored. As described on page 7, we will ensure that the data generated is subjected to rigorous trustworthiness procedures.

Refugee participants will complete questionnaires agreed by the co-design members and the refugee involvement group. We will aim to collect a minimum of 15 and a maximum of 30 questionnaires at the start of peer-support, then 3 and 9 months later. Questionnaire data will be compared to qualitative data to assess if the selected measures are capturing meaningful and valid data, and the degree missing of or incomplete data. Focus groups with peer-support workers will explore their experience of delivering the model and identify barriers, facilitators, and areas for refinement.

5 STUDY SETTING

Plymouth:
There are four dispersal areas for asylum seekers in the South West. These are Plymouth, Bristol, Gloucester and Swindon. The Home Office currently disperses more refugees to Plymouth than to Bristol – a city more than twice its size. Plymouth's population is 93% white British; Bristol's is 78% (ONS, 2013). Plymouth has resettled 200 Syrian individuals under the Syrian vulnerable persons' scheme and was committed to settle 60 more Syrian people in an extension to this scheme by April 2020. However, this was delayed due to COVID-19. The numbers of Plymouth-based asylum seekers remained static over the past 12 months with local data showing there were 350 people with asylum seeker status. This does not account for the hidden, unofficial population not eligible for HO support as asylum seekers who are primarily without recourse to public funds and whose numbers are thought to be growing. Along with national trends, these numbers are likely to rise (Walsh, 2019; UNHCR, 2020). Refugees in Plymouth are mainly from Ethiopia, Sudan, Syria, Iran, Somalia, Palestine and Iraq. Refugees speak a variety of languages, have a range of different needs and skills, but statutory services are struggling to meet their needs within existing provision. In the UK, services to refugees are increasingly outsourced to third sector organisations such as START (Butler, 2005).

START has established good links with refugees in the community and provides the ideal setting and model to extend the reach of mental health and wellbeing provision to these groups. It is a non-governmental organisation that works in partnership with families, individuals, and organisations to facilitate the transition of refugees from people in need to self-reliant contributors to their local communities. START recognises the skills and experiences that refugees bring to Plymouth, adopting a strengths approach with those whom they work with. START utilises student placements as a resource which together with the strengths and skills of the community provide a range of support to refugees. The organisation began in 2001 as a collaboration between the Social Work Placement Co-ordinator at Plymouth University (Avril Butler, now Bellinger), the City Council's Ethnic Minority Achievement

Service and Social Services. Although initially a casework service for people with leave to remain (1400+ refugee households to date), START developed a range of inclusive activities that remain core to the work of the organisation: Job Club, Walking Group, Cultural Kitchen, Women's Group and an Allotment.

Plymouth is unique in having a specialist service for the diagnosis and treatment of mental health issues in refugees (Livewell). Because of high demand that cannot be met by the secondary services, Livewell is supporting two outreach projects being piloted with third sector agencies. The first offering a mental health triage service operated by Devon and Cornwall Refugee Service (DCRS) offering supervision to caseworkers. The second is joint working with START addressing the health needs of complex families on the Vulnerable Persons Resettlement Scheme. The proposed project will build on the experience of this integrated model of working and extend its reach by training PSWs.

Gloucester:

Gloucester is one of the South West's dispersal cities for asylum seekers and resettlement areas for refugees. It has one strong and well-established non-governmental organisation, GARAS that supports refugees and asylum seekers across the city. Like START they offer a range of services, including health advocacy and advice, counselling and signposting to other services. Gloucester has a smaller population than Plymouth 128,000 vs 262,000 and is more racially diverse e.g., 84% of residents are White British compared to 93% in Plymouth. The rest of the population identify as South Asian (3.5%), Black British or Black (2.8 %), Chinese or Other Asian (1.3%), Mixed Race (3%), while 0.3% identify as another ethnicity with the remainder identifying as other White. These similarities and differences make Gloucester a good second study site in which to pilot test the model. It has the infrastructure to help support the delivery of the intervention and a refugee population with similar needs. Every person eligible to take part in this research will be offered the same opportunities in line with the NIHR guidelines.

PSWs will have a base in the community and will have designated spaces to work with refugees at START, GARAS and HeadSpace. PSWs will also meet refugees in community settings such as faith-based sites, local authority offices and other community buildings holding drop-in services for refugees. PSWs will work in conjunction with Livewell, GARAS, START and HeadSpace to deliver this culturally appropriate peer-support model in a flexible way to meet the needs of refugees. HeadSpace have been delivering peer-support in the community for a number of years and are currently commissioned by NHS DEVON Clinical Commissioning Group to deliver this for the majority population of Plymouth. Our PSW will extend the reach of these organisations and link them to other statutory and non statutory providers.

6 SAMPLE AND RECRUITMENT

6.1 Eligibility criteria

6.1.1 Inclusion criteria

Phase 1:

Refugees - Focus Groups and Interviews:

1) 18+ years
2) Refugee or asylum seeker

3) Seeking help or support for mental health issues or distress
4) Can give informed consent

Professionals - Focus Groups and Interviews:

1) Working with or providing support to refugees or asylum seekers
2) Any grade or discipline
3) Part time, full time or agency staff

Phase 2:

Co-Design Members:

1) Any refugee or professional willing to take part

Peer Support Workers:

2) Adults (aged 18 and over)
3) Proficient English
4) Settled status in the UK after arriving as a refugee or asylum seeker
5) An interest in mental health and peer-support
6) Good interpersonal skills

Phase 3:

Refugees – Interviews and observations

1) 18+ years
2) Refugee or asylum seeker
3) Seeking help or support for mental health issues or distress
4) Can give informed consent

Peer Support Workers:

1) Working with or providing support to refugees or asylum seekers

6.1.2 Exclusion criteria

Phase 1:

Refugees:

1) Unable to provide consent
2) Severely ill and requiring immediate ambulatory care

Professionals:

1) Professionals not working with refugees or who have no experience of working with refugees

Phase 2:

Co-design Members:

1) Not working with refugees and no prior experience of forced migration

Phase 3:

Refugees:

1) Unable to provide consent
2) People experiencing a relapse of mental ill-health (to ensure participant wellbeing)

Co-design Members:

1) Not working with refugees and no prior experience of forced migration

6.2 Sampling

6.2.1 Size of sample and sampling technique

Throughout the whole project, where possible all interviews and focus groups will be conducted in person and in venues chosen by participants. We will provide the opportunity to for people to attend university venues if they wish, or at various community venues provided by START and GARAS. Participants will also have the opportunity to be interviewed at home should they wish to do so. Interviews will typically last about 1 hour. We will employ interpreters if required and these individuals will sign a confidential agreement and be trained in research interpretation by the team.

Phase 1:

Refugee Interviews:

For interviews and focus groups a purposive strategy will be employed to ensure that all the main refugee groups are represented across our two study sites. We will also ensure that where possible our sample will reflect a range of ages and that equal numbers of men and women are included. We aim to interview 10 refugee participants in total; 5 at each site (Plymouth and Gloucester). The EBCD toolkit recommends between 5 to 15 participants for service user interviews (King's Fund 2013). Recruiting up to 15 will help alleviate against no shows and drop outs.

Refugee Focus Groups:

To maximise the participation of refugees who may feel more comfortable talking with similar people in a group setting we will conduct focus groups (x2 n= 6-8 people in each). It may be necessary to provide women and men only focus groups if mixed groups present a barrier to participation. There may be other characteristics that warrant the composition of specific groups, these will be decided in line with our co-design principles, our PPI group and the needs of the participants.

Professional Focus Groups:

Purposive sampling will ensure that all the main agencies working with refugees in Plymouth and Gloucester are represented at focus groups based on gender, ethnicity, religion, and professional grade (x2, n=6-8 people in each group). Three focus groups will be conducted. The EBCD toolkit recommends recruiting five to 15 participants for staff interviews (King's Fund 2013). Based on this figure we aim to recruit approximately 16 participants across the two focus groups, to help mitigate against no shows and drop outs.

Celebration Event:

It is hard to predict how many participants will attend this event (King's Fund 2013), however past EBCD studies have recruited approximately 10-64 staff (Blackwell et al. 2017). We anticipate that the participants who take part in the interviews and focus groups will also attend these events, plus key stakeholders from partner organisation *n* = 40.

Phase 2:

Co-Design Members:
Refugees (n= 7) will be invited to participate in the co-design workshops. A convenience sample will be employed working with START and GARAs to ensure where possible the main refugee groups are represented (e.g., by ethnicity, religious and linguistic group). We will attempt to recruit equal numbers of men and women. We have planned for 8 co-design workshops over Phase 2 of the study. We will aim to support a core number of refugees to attend as many sessions as possible, but there are likely to be people who are unable to make all of them. We anticipate that up to 20-25 refugees will be involved in these activities. They may or may not have taken part in phase 1 data collection and this will not be a barrier or expectation of workshop membership.

Professionals:
7 professionals from provider organisations will be invited will be invited to participate in the co-design workshops. A convenience sample will be employed to ensure that provider organisations and professionals from a range of disciplines are involved.

Research Team (n=6) members will form part of the co-design team; Professor Glenn Robert, SRF (TBC), Dr Helen Lloyd/Debra Westlake, Research Assistant/Dr Sana Murrani.

Celebration Event:

As described above It is hard to predict how many participants will attend. We anticipate that the participants who take part in the design activities, and previous interviews and focus groups may also attend this events, plus key stakeholders from partner organisation *n* = 50.

Phase 3:

Sampling for Acceptability and Feasibility Test

We will endeavour to recruit representative samples of refugees for all aspects of the acceptability and feasibility test. This will involve representing the variety of religious, ethnic, and linguistic groups resident in Plymouth and Gloucester. For example, we will proactively ensure our samples represent people from Ethiopia, Sudan, Syria, Iran, Somalia, Palestine, Iraq and Ukraine, and seek to actively recruit refugees from smaller minorities e.g., Kurds. We will ensure representation from both men and women, and a range of ages, and provide support and flexibility to maximise the participation of people with children, those who are caring for others and those who have disabilities.

60 refugees will be recruited to take part in the trial who represent the refugee communities present in Plymouth (n=30) and Gloucester (n=30).

A minimum of 15 refugees who participate in the trial will be asked to complete outcome measures at baseline, 3 and 9 months (8 in Plymouth and 7 in Gloucester).

16 refugees will be recruited to using a maximum variation sample to take part in qualitative interviews at 3 & 9 months (8 Plymouth, 8 Gloucester).

8 refugees (4 Plymouth, 4 Gloucester) will be approached to have their interactions with a PSW observed. This will ensure that each PSW will be observed and we will use this data to refine our delivery, training, support processes and up date our Programme Theory. These observations will be take place using a convenience sample, but will as far as possible attempt as a basis to represent different gender identities and different racial and linguistic groups

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Celebration Event:

As described above It is hard to predict how many participants will attend. We anticipate that the participants who take part in the design activities, and previous interviews and focus groups may also attend this events, plus key stakeholders from partner organisation *n* = 60.

6.3 Recruitment

We work with local authority and NGO data to ensure our recruitment activities reach the refugee groups resident in both sites to ensure our recruitment methods and consent processes are practical and Fair. This could involve an interpreter to ensure potential participants are fully aware of the expectations regarding participation, but also to ensure that no one is excluded on the basis of language and to communicate the ethical practices that the team will engage in to protect the dignity and rights of participants. START & GARAS work with interpreters on a regular basis and have local knowledge on who are suitable to this work and how to engage them. We have budgeted for interpreter time and also the costs of childcare to ensure that parents are not prevented from participation based on childcare responsibilities.

Once ethical approval has been gained, participants will be recruited in the following ways:

Phase 1:

Recruitment of Refugee and Professional Participants

1) Posters about the research will be placed in all participating services (START, GARAS) and translated into the main languages of refugees in Plymouth and Gloucester.
2) Workers at each service will be encouraged to advertise the study to their service users verbally and explain the expectations of the role.
3) The research team will work closely with START and GARAS to identify possible participants by attending community events such as the cultural kitchen in Plymouth, language and support groups (GARAS and START), community allotments and other community activities. Researchers will also help identify professionals working in the community at various non-nhs sites to take part in research activities.

Phase 2:

Recruitment of Co-Design Members:

- Refugees (n= 7) will be invited to participate in the co-design workshops using similar strategies employed for phase 1 but with appropriate material describing the role and expectations of the work.

- Professionals (n= 7) from provider organisations will be invited to participate in the co-design workshops. Posters and presentations at partner organisations will facilitate this.

Phase 3:

Recruitment of Participants for the Acceptability & Feasibility Test:

1) Posters advertising the PSW trial will be placed in partner organisations in the community to publicise the trial.
2) START and GARAS will actively recruit for the trial and will receive CRN funds to support this work. The research team will also support these activities.
3) When contact has been made and participation explained, informed consent processes for participation in the trial will be commenced. This could involve and interpreter and/or use of translated materials in the relevant language.

6.3.2 Consent

Written informed consent will be obtained from all participants; they will be provided with written and spoken information in their chosen language. The information sheet and consent form have been designed with advice from people with experience of seeking asylum and refuge in the UK. They explain the purpose, processes, activities, potential risk and benefits of participation. If written materials are not appropriate to use with someone, the research team will engage an interpreter to explain the study verbally by phone or in person. It will be emphasised that participation is voluntary and that they can withdraw their consent without having to explain why. They will be told clearly that their decision on whether to participate in the study, will not affect the service they receive nor their status with the Home Office.

It will be ensured that participants have sufficient time to seek advice about whether to participate and ask questions about the study before giving consent. They will be offered to bring someone with them to the interview, and also to have an interpreter present.

It will be made clear to all participants that taking part in the study will not impact on their access to services and that data will be anonymised. Identifiable personal information will be separated from data collected. All information and data will be stored securely, and this will be clearly explained. The usual processes and ethical requirements for research will be adhered to and all participants will be made aware of their right to withdraw consent, how their data will be processed, stored and protected and their rights to confidentiality as per current GDPR guidance. Participants (professionals and refugees) will be provided with information and consent forms relevant to the activity that they are taking part (e.g., either data collection, co-design or acceptability test). The process of gaining informed consent is as follows:

1) Study researchers will verbally explain the study to the potential participant, using the information sheet as a prompt and any other helpful materials as described above. This will be available in different languages and where necessary we will involve an interpreter
2) If interested, the researchers will provide the potential participant with an information sheet and consent form (in the appropriate language)
3) Time will be provided to allow the participant to ask questions

4) Researchers will explain to the participant that they have at least 24 hours to decide whether they wish to be involved in the study, this will allow them time to discuss participation with carers/other staff etc.
5) Before interview/focus group/research activity the researcher will again check with the participant if they have any questions
6) The participant and researcher will then complete and sign the consent form

Refugee participants may invite a friend or family member to research activities should they wish to. Researchers will give potential participants an information sheet and consent form for the friend or family member, and will collect their consent form on the day of the activity that will be attended.

Although refugees are considered a vulnerable group because of the nature of their experiences, we will not recruit anybody who is actively experiencing serious health issues that require emergency care. Our team will ensure that when signing the consent form the potential participants are able to repeat back the key information to show they understand what taking part in the study means.

Capacity will be assessed in the following ways:

1) understand the purpose and nature of the research
2) understand what the research involves, its benefits (or lack of benefits), risks and burdens
3) understand the alternatives to taking part
4) be able to retain the information long enough to make an effective decision
5) be able to make a free choice
6) be capable of making this particular decision at the time it needs to be made

Issues related to observations of meetings:
A researcher will observe and audio-record meetings between refugees and peer support workers. Meetings will not be audio-recorded if refugees find the recording uncomfortable. If refugees are accompanied to meetings, it will be ensured that verbal consent to being observed and audio-recorded is obtained from everyone in the room, including the interpreter or someone else present. Field notes will be written in the researcher's diary and will not contain personal identifiable data of anyone present at the meeting or consultation.

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6.3.3 Participant payment

1) Refreshments (and where relevant lunch) will be provided at all EBCD events

2) Refugees can claim back travel costs

3) Refugees will receive a £20 voucher (or cash) for taking part in interviews and £10 for focus groups.

4) Peer Support Workers will receive the same payment for interviews and focus groups as they will for their support role (£40/hour).

5) Service provider staff will receive a £10 voucher for participating in interviews, focus groups and co-design workshops.

6) Refugees will receive a £30 voucher for taking part in co-design workshops and the PPI group meetings, and childcare will be provided. The higher amount takes into account the length of the workshops.

7) Refugees and peer support workers will be provided with a mobile phone and a contract for the duration of the study.

7 ETHICAL AND REGULATORY CONSIDERATIONS

Confidentiality:
Procedures will be conducted under the guidance of the Data Protection Act 1998 and the General Data Protection Act 2018. Identifiable information e.g. participant names, will be kept separately to other data in password protected files, with further protection from the University of Plymouth firewall. All data will be stored on a secure drive and never on local PCs or mobile devices. Participants will be given anonymised participant identification numbers to be used on all data collected.

As part of the research activity may involve filming refugee interviews; we will protect their anonymity using blurred video and voice modification software if this is requested. If sound clips are to be used we will use a voice over who is not the participant unless they specifically want to retain their voice. In the majority of cases, due to the sensitive position of refugees, interviews will be audio recorded, and sections of it will be edited into a short 30 minute audio clip that will be shown to NHS staff, NGO staff and refugees and other professionals who join co-design event. The purpose of using audio clips is to ensure that the refugee voice is amplified to best convey the their experiences of service contact or experiences of distress. Audio clips or recordings will be played at the co-design event (with consent) and to stimulate discussion of co-design priorities between professionals and refugees at the joint co-design event. Participants will have the option of participating in the making of this clip if they so wish. We will limit the information available on the clips. Any detail regarding identifiable information such as name, conditions, dates of service use or address will be available only to the research team during the project. It will then be destroyed at the end of the project. Participants are informed of this in the information sheet. They are encouraged to ask any questions or raise concerns throughout the process and are given a two stage consent form. The first confirms their initial participation in the study and the elements they wish to be involved in. The second form is given following the interview, confirming their consent to release their rights to audio (or where relevant filmed) interview data to the University of Plymouth for its use in the project and future educational and co-design work.

Capacity:
As the research entails participation of people who have suffered or are suffering trauma or distress, all attempts will be made to ensure participants have capacity to consent to partaking in the study. This will be ensured by following the principles set out in the Mental Capacity Act (2005). As per the eligibility criteria, refugees will be excluded from the study if they require immediate ambulatory care, or if they are currently experiencing a relapse of mental ill health. We do not plan to recruit people who lack capacity.

Disclosure of harm:
The research team will always report potential and/or actual harm, despite the effects it may have on the study. Participants will be made aware in the information sheets of the type of information I would be obliged to report if disclosed/observed.

Disclosure of legal status:
The research team will not ask participants information about their legal status with regards to their arrival in the UK, since this is not a requirement participation. The team will however make each participant aware that if they do disclose that they are in the UK illegally, that the team will have a legal responsibility to report this to the Home Office.

Refugee, Peer Support Worker and Team well-being:

Support and safeguarding for members of the Public Involved in the Project:
Appropriate training, supervision, and on-going support will be provided to all members of the public that are involved in this research in any capacity.
For example, this might include:

- PPI members on our advisory committee
- Members of the public taking part in co-design activities
- Refugees who become peers support workers
- Interpreters

Livewell, Colebrook, GARAS and START currently employ peer support workers and have established training for PSWs and interpreters on a range of issues including and not limited to safeguarding, managing risk, confidentiality, self-care, tailored and culturally relevant relational skills, team working, competencies for organisations hosting PSWs and safe working environments. Clear protocols will be provided within the delivery manual to guide PSWs and interpreters on these important issues. In addition to this, core elements of the Peer Support Worker Competence Framework for Mental Health will be incorporated into our manual to ensure our model is in line with that proposed by Health Education England for the NHS Long Term Plan. Specifically, PSWs will follow health and safety induction programmes provided by their host organisation (e.g. Livewell or GARAS). CI Parham will incorporate peer support training offered through Colebrook into the PSW training programme during the design workshops. Support for working with refugees will also be provided through Livewell and GARAS. This is likely to include British Psychological Society guidelines for working with refugees and asylum seekers (Tribe) will be included in the training of PSWs.

Risks to the researcher:
Study activities will be conducted at the university or community centres (workshops), service providers (observations and interviews) and, when a refugee expresses a preference for it, in someone's home. There is a potential safety risk to the researcher when conducting study activities outside of service or University premises. Therefore steps have been put in place to reduce the risk as per the
Code of Practice for Social Researchers developed by the Social Research Association (https://the-sra.org.uk/SRA/Resources/Good-practice/SRA/Resources/Good-Practice.aspx?hkey=ccb6430d-24a0-4229-8074-637d54e97a5d). A Fieldworker Risk Assessment will be carried out prior to a home visit (ADD).

A list of addresses, names and contact details of participants will be given to the chief investigator (or nominated lead researcher) prior to the interviews being conducted. The researcher will call the chief investigator (or lead researcher) on arrival to the data collection site and again when the researcher has left. If the chief investigator (or lead researcher) has not heard from the researcher within a set time frame they will phone the researcher. If they are unable to make contact they will follow the necessary steps.

Participant benefits:
Refugees who take part in interviews will be paid £25, and professionals will receive a £10 gift voucher. For focus groups refugees will be paid £15 for taking part and professionals will receive a £10 gift voucher. Travel expenses will also be paid. Peer support workers will be paid £40 per for hour delivering the intervention and for any associated research participation. For half day co-design workshops refugees will be paid £30 (£60 for a full day). Staff will be provided with a £10 gift voucher. Refugees and Peer support workers will be provided with a mobile phone and a mobile phone contract for the duration of the study. Child care costs will be covered if required to enable parents to take part in the study for any activity. Taking part in the research will enable both staff and

refugees to have their voices heard and be equally and actively involved in the co-design of an intervention to support refugee mental health. Peer support workers and co-design members will be provided with training and gain new skills. They will also improve their CVs and benefit from enhanced employment opportunities. We hope that the information collected and the resulting intervention will help improve the refugee mental health and wellbeing.

The EBCD process has been shown to improve service-user/service-provider relations, and the service-user facilitators who will be trained to carry out EBCD will benefit from gaining skills in this methodology and will be able to apply this to any future service improvement work they may wish to conduct.

7.1 Assessment and management of risk

The processes of seeking asylum and leave to remain, and establishing oneself after these have been granted, are stressful and traumatic. The research team has previous experience of working with refugees and two members of the team will be peer-researchers, recruited through the partner agencies. The chief investigator Helen Lloyd will ensure the team has training on how to behave in a culturally sensitive way when approaching potential participants. Sensitive or upsetting topics are likely to arise in interviews and/or group discussions. If participants become distressed or upset at any point during study activities, the researchers will offer to stop the session and will only recommence if and when and the participant is ready to do so. There will be no pressure on the participant to continue. Continuous assessment will be made looking for non-verbal cues to discomfort and participants will be asked if they are still willing to go ahead with participation if anything suggests that people are withdrawing consent, whether verbally or through non-verbal expressions (e.g. looking anxiously at the recorder or observer, appearing to hold back information that is asked for and similar).

If applicable, concerns about someone's wellbeing will be referred on to the clinical team at partner agency and research site Livewell, which delivers specialist mental health service for refugees. If the participant shows any evidence of suicidal thoughts or ideation, their clinical team will be informed immediately as guided by the researcher's professional conduct and standards (Social Research Association Good Practice Guidelines). In the event that participants disclose an incident that may cause direct harm to any member of the public including themselves, the researcher will report this, despite the effects it may have on the study. If the individual is a staff member, normal escalation procedures will be followed. If the disclosure is from a refugee, the primary supervisor will be notified immediately to decide on the appropriate course of action. However, the researcher will also act within the boundaries of their professional code of conducts/standards and has a duty to protect the public. Participants will be informed through the participant information sheet about the type of information that the researcher would be obliged report.

Participants will be informed that their study participation is completely voluntary. There may be some inconvenience to participants when attending study activities. As much as possible, the lead researcher will ensure that study appointments coincide with their normal engagement with service providers to minimise inconvenience with regards to time and travel. Refugees will be reimbursed for their travel expenses to any research activity and paid for their time.

7.2 Research Ethics Committee (REC) and other Regulatory review & reports

This study has been approved by the University of Plymouth, Faculty of Health Research Ethics committee (20/10/22). Before the start of the study, a favourable opinion will be sought from an NHS REC for the study protocol, information sheets, consent forms and other relevant documents e.g. study recruitment posters and topic guides.

Additionally:

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.
- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

7.2.1 Regulatory Review & Compliance

Before the site can enrol participants into the study, the Principal Investigator will ensure that appropriate approvals from the NHS REC, the UoP Ethics committee and UoP Sponsor are in place.

For any amendment to the study, the Principle Investigator, in agreement with the sponsor and supervisory team, will submit information to the chair of the authorising REC in order for them to issue approval for the amendment. The Principle Investigator will also work with all recruitment and research sites to ensure that they are aware of and are able to implement any amendments to the study.

7.2.2 Amendments

The lead researcher and supervisory team will be responsible for the decision of making any amendments to the study protocol. Any amendments will be sent to the chair of the authorising REC who will decide whether the amendment is minor or major. Protocols will be dated and include the version number.

7.3 Peer review

The study protocol has been reviewed by the co-applicant team, and a panel of experts from the NIHR.

7.4 Patient & Public Involvement

The following PPI has been/will be sought for this study:

The success of this study depends on refugees, service providers and academic researchers working together. We will do so at all levels of the study.

There are three main components of this study, where refugees will be involved:

1. The development of the peer support model will fully involve refugees in the co-design workshops. Here they will help analyse findings from interviews and identify what good looks like in support provision.

2. The model itself will involve refugees as peer-support workers, and they will be part of developing this form of support.
3. The study team will work with refugees at management level as co-applicants, refugees will be members of the study team and hold governance roles.
4. A refugee PPI group will review study materials and guide the research team in relation to culturally sensitive practices.

PPI at management level:

Abdullah is a co-investigator (CI) with refugee and service use experience, and is a support worker with Livewell. He will advise CI Liabo, who is the PPI lead, on a culturally appropriate approach to PPI. CI Liabo will have responsibility for ensuring that the partnership with refugees is in line with the NIHR standards for public involvement. Jointly they will also draw on the literature on co-production and involvement of refugees in research.

PPI at study team level:

We will recruit two refugee peer-researchers to be part of the study team. They will receive research training and be fully involved in planning, conducting and analysing interviews and co-design workshops.

We will also establish a PPI reference group of refugees who will review study plans and materials and feed into the key decision points. The training provided for this group will be agreed jointly with the group, depending on their learning preferences and needs. This will be discussed and planned at the beginning of the study. The study team will ask each PPI member what their preferred communication channels are and ensure they are kept informed about the study progress and activities. A member of the study team will be a named contact for the PPI group to ask about meeting arrangements and to contact for help with accessing meetings.

We have budgeted for a substantial number of PPI meetings to ensure we have infrastructure to support extensive involvement of refugees in the study. We have budgeted for service users' travel, time and subsistence at meetings. To ensure inclusive meetings we have costed for interpreters and childcare costs. We will assess all meeting venues for disability access and provide additional support should anyone need it at meetings.

If deemed appropriate at the start, middle and end of the study we will use an adapted version of the PiiAF framework (http://piiaf.org.uk/) to capture impact of the involvement of refugees in the study. We will be mindful of not over-using formal tools and feedback forms in a study where the involvement is so integral to the design, and much of the impact will be captured by the study design itself. Co-production and results from this will be part of the reporting of the study's main findings.

PPI at governance level:

Our local reference group and the national advisory group will have membership that includes people with refugee background and experience.

7.5 Protocol compliance

Accidental protocol deviations can happen at any time. They will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

7.6 Data protection and patient confidentiality

The sponsor and data controller for this project will be University of Plymouth (UoP). The University will process personal data for the purpose of the research outlined within this protocol. The legal basis for processing personal data for research purposes under GDPR is a 'task in the public interest'. Participants can provide consent for the use of their personal data in this study by completing the consent forms provided to them. The lead researcher will be the data custodian. To reduce the risk of identification, identifiable and anonymised data will be stored in separate locked cabinets, in password protected files that are protected by the UoP security protocols. Locked cabinets will be kept in an office at the UoP which has authorised swipe card access only.

Focus groups and interviews will be recorded on an encrypted digital audio recorder and will be securely transferred to a UoP password protected server. They will either be transcribed by the researchers on a UoP password protected server, or may also be uploaded in encrypted form to a professional transcription website. Only University-approved data transcription websites will be used. Transcripts will be downloaded from this website to the UoP password protected server. Transcripts will be anonymised and uploaded to NVivo application (QSR International) software within a UoP password protected server. Data analysis will be conducted by the research team and will be scrutinised by the supervisory team.

All qualitative observational data (e.g. observations of support interactions and observations of EBCD events) will be completed in either paper form as field notes or on a lap top computer, either at a community setting or at the EBCD events; the field notes will not contain any information about specific participants as the data will be looking broadly at activities, interactions, group dynamics, fidelity of the EBCD process and intervention and rather than specific people. The data will be manually uploaded into the qualitative analysis package NVivo application (QSR International) software within a UoP password protected server, then analysed by the lead researcher.

All structured observational documents and self-report questionnaires will initially be completed in paper form or on a lap top computer, at the participating community settings; This will not contain any identifiable information. The data will be manually uploaded into the statistical software package SPSS on a UoP password protected server, then analysed by the research team.

Procedures for anonymisation:
Each participant will be given a unique participant identification number at consent stage. Focus group and interview data will use this number and not the participant's name. Focus group and interview data will be transcribed and anonymised to ensure participant's name, location or any other identifying information is removed. Each transcript will be given the participant identification number. Audio recordings will be deleted following transcription. The key that re-links the study ID to personal details will be kept in a separate locked cabinet, at the UoP school of Psychology or in a password protected electronic file stored on an encrypted server and will not be stored near any participant data.

Anonymised quotes used in any publications and/or conference presentations will be scrutinised to ensure that a person cannot be identified from the combination of quotes.

Audio or film clips will be anonymised using blurring and/or voice changing software. Recorded clips will only be used in their edited form if written consent has been provided by the individual participants. Photographs taken at the co-design events will be used in dissemination activities such as presentations or online, only if participants

have indicated their willingness to be photographed by putting a green sticker on their name badge. A red stick indicates the participant does not want to be photographed.

Paper copies of the study data will be archived for 7 years in UoP secure facility on completion of the study. All contact details will be destroyed on completion of the study. Audio recordings will be deleted once analysis has been completed.

7.7 Access to the final study dataset

Information will be accessible to the following people:

- Research Fellow, Dr Hoayda Darkal
- Research Fellow, Wen-Yu Wu
- Chief Investigator, Dr Helen Lloyd and the co-applicant team

Authorised individuals acting on behalf of the sponsor, UoP, may also request access to information. Participant Information Sheets state that supervisors and the sponsor may have access to data and consent will be sought.

8 DISSEMINIATION POLICY

8.1 Dissemination policy

The research will be written up for an NIHR HSDR Report and subsequent publications. All data from the study is owned by the University of Plymouth.

Refugees:

1) A plain English summary of the findings will be written in collaboration with the PPI group and translated into the key languages representative of the refugees in Plymouth and Gloucester
2) Presentations in conjunction with PPI group at relevant conferences

Professionals and Provider Organisations:

1) Disseminated directly into professional practice through the research team and research partners directly and indirectly involved with the EBCD process
2) Published in open access peer-reviewed journals appropriate for reaching the target audience to influence practice
3) Presented as oral/poster presentations at national and international conferences e.g. European Conference on Mental Health (and European Conference on Mental Health Service Evaluation (http://www.enmesh.eu/)
4) Teaching sessions to undergraduate/postgraduate nurses at UoP, University of East London and Kings College London about the findings of the research and the research methods used
5) At the EBCD celebration event, provider organisations will be invited and members of the PPI team will be supported to disseminate the findings from the project to date. This is likely to include information about the intervention and how it was implemented into practice

Academic colleagues:

1) Publications will be available and promoted to academic colleagues and students throughout the faculty via UoP newsletters
2) Details of publications will be uploaded onto the study website and co-applicant profiles

Wider national/international audience:

1) Infographics of the key findings will be posted on the study Facebook page, Twitter, and Instagram sites with a link to any resulting publications
2) The research team will post on blog sites such as The Conversation and the Mental Elf and service-user websites such as Mind

8.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship of the final study report will be granted to the Chief Investigator, the co-applicant and research teams.

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1. APPENDICIES

11.1 Appendix 1- Required documentation

Miscellaneous:
IRAS
Schedule of events
Statement of activities
NIHR NHS costs spreadsheet
Dr Helen Lloyd CV
Indemnity insurance letter
NIHR scientific review letter
Honorary contract from UoP
UoP insurance
Recruitment posters:
EBCD invitation posters
Posters to recruit refugees and professionals into EBCD
Recruitment invitations/cover letters:
Invitation/map to co-design event
Invitation/cover letter to interview – staff, pt. and carers
Invitation/cover letter to focus group – professional, pt. and carers
Data collection materials:
Topic guide (EBCD refugee interview)
Topic guide (EBCD staff focus group)
Topic guide (PSW interview)
Observational grid
Consent and information sheets:
PIS professional EBCD
Consent professional EBCD – focus groups
Consent professional EBCD – Celebration event
Consent PSW - observation
PIS refugees EBCD
Consent refugees EBCD – interview
Consent refugees EBCD – Celebration event
Consent refugees - observation
PIS PSW interviews
Consent PSW interviews
Audio/video Clip release form

13.2 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1	18/10/22	HD	Added text to convey that only approved transcription services will be used.
2	2 & 3	8/7/23 18/7/23	HL	2 Iterations to text re movement of observations to phase 3 and removed references to peer researcher as per NIHR guidance.

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.