



**Effectiveness and cost-effectiveness of a peer-delivered, relational, harm reduction intervention to improve mental health, quality of life, and related outcomes, for people experiencing homelessness and substance use problems**

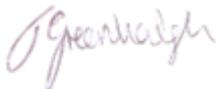
**'The SHARPS cluster randomised controlled trial'**

**Process Evaluation Analysis Plan V1.0 [03/10/25]**

**Based on the Protocol Version v6.0 [10/07/25]; Statistical Analysis Plan V1.0 [24/07/24], HEAP V1.0 [02/10/25]  
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## Amendment History

PEAP Version	Protocol Version	Section changed	Description and reason for change	SHARPS Team/ Statistician	Date changed (changed by)

### 1. Study design

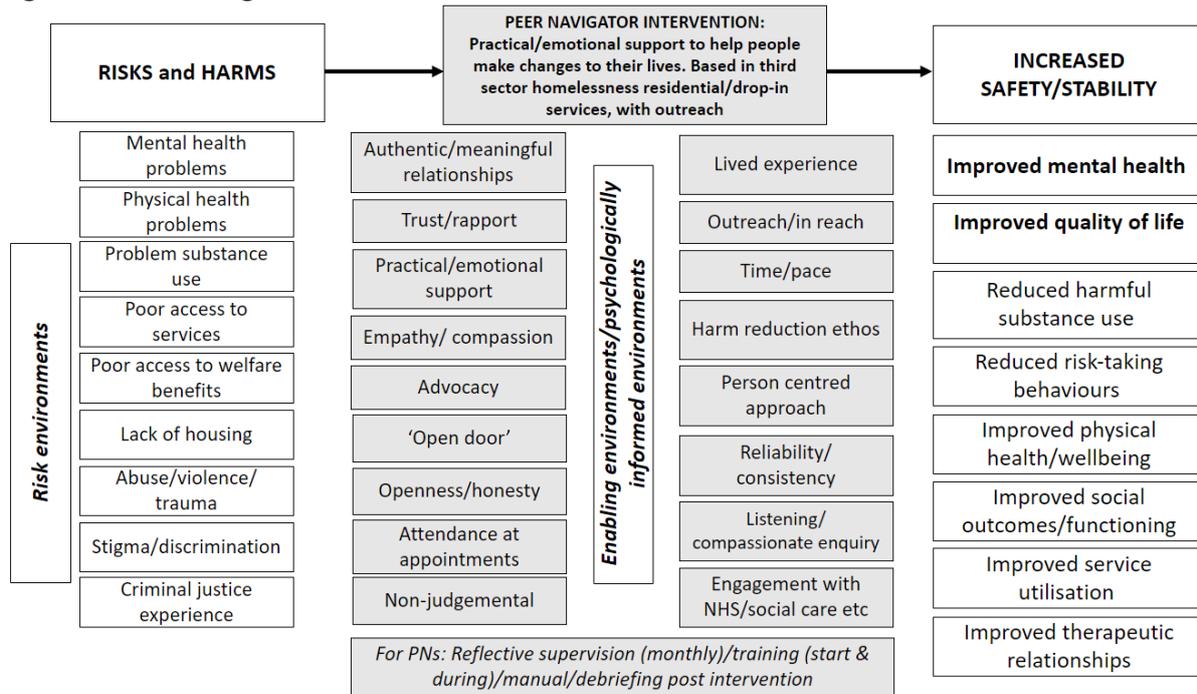
We will use a mixed methods design for our process evaluation drawing on the MRC guidance on process evaluations of complex interventions (1) and informed by Normalisation Process Theory (NPT) (2). NPT comprises four components: coherence (understanding), cognitive participation (buy-in), collective action (making it work), and reflexive monitoring (on-going appraisal). As part of the process evaluation, we will also take a quantitative approach to assess intervention fidelity which will include the use of an adapted existing fidelity index completed by the Peer Navigators and their line managers (3).

Our process evaluation aims to:

- 1) investigate transferability to UK public sector settings wider than third sector, and international settings
- 2) examine 'fit' of intervention to context/population
- 3) assess adherence/fidelity to assess intervention effect more broadly

This evaluation will provide essential knowledge for future roll-out/implementation of the intervention beyond trial conditions. Figure 1 illustrates our trial logic model.

**Figure 1. SHARPS logic model**



A summary of the timings of process evaluation data collection (both quantitative and qualitative) is displayed in table 1.

**Table 1:** Summary of process evaluation data collection.

	Baseline	6m	12m
<b>Qualitative</b>			
Semi-structured interviews with intervention participants (n=40)			✓
Semi-structured interviews with staff in both trial arms (n=19)			✓
Semi-structured interviews with external stakeholders in both arms (n=19)			✓
Semi-structured interviews with Peer Navigators (n=9)	✓		✓
Semi-structured interviews with TSA Addictions team (n=2)			✓
Semi-structured interviews with trial core team and researchers (n=10)			✓
Non-participant observations in both arms	✓	✓	✓
Peer Navigator diaries (bi-monthly)	✓	✓	✓
<b>Quantitative</b>			
Peer Navigator outcomes (Professional quality of life (ProQOL) and Job Satisfaction Survey (JSS)) (n=9)	✓		✓
Support Worker outcomes (ProQOL, JSS) (n=10)			✓
NoMad measure with Peer Navigators (n=9)	✓	✓	✓
NoMad measure with intervention staff (n=45)	✓	✓	✓
<b>Fidelity</b>			
Peer Navigator content fidelity checklists	✓	✓	✓
Peer Navigator training logs			✓
Line Manager role fidelity survey		✓	✓

## **2. Qualitative data collection, management, and analysis**

### Data collection and management

#### *1) Interviews*

Semi-structured online interviews will be carried out with all Peer Navigators across the intervention study sites at baseline (prior to working with their caseload) and at 12 months (when they have stopped working with their caseload). Qualitative interviews will be carried out by the Stirling research team who will follow the interview topic guide for Peer Navigators co-developed by the SHARPS Experts by Experience (EbyE) group.

Semi-structured face-to-face/telephone/online interviews will be carried out with a sample of intervention participants across intervention sites at the 12-month timepoint after they have completed the quantitative outcome measures. Participants will be purposively sampled and offered the opportunity to complete an interview. Before approaching participants, the distribution of age, sex, and ethnicity will be checked to ensure the sample is representative of demographic characteristics in that cluster. Qualitative interviews with intervention participants will be carried out by research assistants and follow the interview topic guide for intervention participants co-developed by the SHARPS EbyE group. Intervention participants will receive a £25 shopping voucher at the end of the interview as a thank you for their participation. A smaller sample of participants in the two intervention sites where the Peer Navigator left early will also be attempted at the 12-month point.

Semi-structured online interviews will be carried out with The Salvation Army (TSA) staff in the intervention and control clusters and also with local commissioners in the area, where possible. In the intervention sites, the Peer Navigator's line manager will be approached for interview and in control sites it will be the Service/Programme/Project Managers.

Semi-structured online interviews will also be carried out with staff members from TSA Addictions Team, the core SHARPS research team, and a sample of the research assistants at the end of the study period once all clusters have completed 12-month follow up.

We expect all interviews listed above to last between 30-45 minutes. All online interviews will be conducted via MS Teams and all interviews will be audio-recorded (with permission) using an external audio recorder. After the interview has been conducted, the researcher will immediately upload the audio file to the appropriate folder on the trial master folder (TMF). If participants do not wish to be audio recorded, notes will be taken instead. All interviews will be transcribed, checked for accuracy, and pseudonymised to remove any potentially identifiable information about people or places, then uploaded into NVivo software. All reported qualitative findings will be pseudonymised and therefore not attributable to participants or places. Interviews with staff members from TSA Addictions Team and the SHARPS core research team are likely to be more identifiable therefore special care will be taken not to use quotes when presenting findings from these interviews, instead high-level themes will be extracted. Transcripts of participant interviews will retain the participant ID number which includes the code for clusters. This will enable analysis of different sites/settings as cases allowing for comparisons, but these will not be reported in any publications.

#### *2) Researcher non-participant observations*

All researchers will complete non-participant observations during every research visit. These observations capture information about the service in terms of the environment, social interactions, activities, and the setting of the town/city the service is based in. Researchers are asked to complete a proforma in as much detail as possible at each visit.

### 3) *Peer Navigator bi-monthly diaries*

Peer Navigators complete diaries every two months, reflecting on their role and being part of the SHARPS study. These are conducted either using audio-recording or word document diary entries.

#### Data analysis

Qualitative analysis will be informed by MRC guidance on process evaluations of complex interventions (1) and by Normalisation Process Theory (NPT) (2). Version 15.1 of NVivo will be used. The NPT coding manual (4) to facilitate transparent data analysis processes and reduce the cognitive and practical burden on researchers. This manual also links the 12 primary NPT constructs to realist evaluation methods by conforming to the Contexts-Mechanisms-Outcomes configuration that realist approaches centre upon. To interpret findings, we will use a range of theories/frameworks, such as the modified access model (which proposes that access to health care systems are the fit between the patient and the health care system in question along dimensions of availability, accessibility, accommodation, affordability and acceptability) by Penchansky and Thomas (1981) (5), and on peer support, such as Barker et al.'s (2020) model of change mechanisms within unidirectional peer support (6). We will examine the impact of the intervention and the role on the Peer Navigators using literature on task shifting, organisational cultures, social bonds, and intersectionality.

Supported by use of theories that can evaluate implementation of complex interventions, such as NPT (2,7), the analysis will identify contextual influences on implementation across settings: how individuals understood, adopted, or perceived the intervention; how participants engaged with/disengaged from the intervention; how staff experienced hosting the intervention and the trial (usual care settings); how the Peer Navigators made sense of role, and other contextual factors impacting delivery. To enhance rigour and validity, the trial EbyE group will participate in data analysis/interpretation to act as a form of 'member checking' with some data sets to enhance the validity and trustworthiness of the findings.

#### 1) *Interviews*

Interviews transcripts will be uploaded into NVivo software for coding. Transcripts will be read in full and then coded deductively using the NPT coding manual, as well as inductively, for any codes that do not fit within this framework. Generally coding will be conducted by one member of the team, with another member checking the coding framework after 2-3 transcripts have been coded. Data from each group will be coded separately in individual NVivo files. Once coding is completed, the data will be sorted into themes and sub-themes with illustrative quotes.

#### 2) *Non-participant observations*

Non-participant observation proformas will be uploaded into NVivo for analysis. The observations will be coded separately for each time point (baseline, 6 months, and 12 months). The observations will be analysed using thematic analysis and the coding framework developed after coding 2-3 observations and checked by another member of the team. Once coding is completed, the data will be sorted into themes and sub-themes with illustrative quotes.

#### 3) *Peer Navigator diaries*

The Peer Navigator diaries will be uploaded into NVivo software for coding. The diaries will be read in full and then coded deductively using the NPT coding manual, as well as inductively, for any codes that do not fit within this framework. Generally coding will be conducted by one member of the team, with another member checking the coding framework after 2-3 diaries have been coded. Once coding is completed, the data will be sorted into themes and sub-themes with illustrative quotes.

### **3. Quantitative data collection, management, and analysis**

#### Data collection and management

##### *1) Professional quality of life (ProQOL) and Job Satisfaction Survey (JSS)*

The ProQOL and JSS will be conducted with Peer Navigators (n=9; at baseline and 12 months) and control site Support Workers (n=10; at 12 months) to assess professional quality of life and job satisfaction. The two surveys are completed online via JISC, with participants being provided with information about the surveys and a link via email. Once all participants have completed the surveys the data will be downloaded from JISC into an Excel spreadsheet for analysis.

##### *2) Normalisation Measure Development Questionnaire (NoMad)*

Peer Navigators and intervention cluster staff (n=4-5 per cluster) will be asked to complete the NoMad survey at baseline, 6, and 12 months to understand implementation processes from those involved in the trial. The survey will be completed online via JISC, with participants being provided with information about the surveys and a link via email. Once all participants have completed the surveys at each time point, the data will be downloaded from JISC into an Excel spreadsheet for analysis.

#### Data analysis

The latest version of R statistical software available at the time of analysis will be used. Given the sample size for the quantitative component of the process evaluation is small, the results will be descriptive.

##### *1) Professional quality of life (ProQOL) and Job Satisfaction Survey (JSS)*

The ProQOL and JSS scores at baseline and 12 months will be downloaded from JISC into an Excel spreadsheet. The Peer Navigators' average score at baseline and 12 months and average change in score between baseline and 12 months will be analysed. Control site Support Workers' average score at 12 months for each measure will be calculated. We will compare Peer Navigator ProQOL and JSS scores at baseline with 12-month follow up. This will assess whether these outcomes improve or decline over the course of the intervention period. Additionally, we will compare Peer Navigator ProQOL and JSS scores with control cluster Support Worker ProQOL and JSS scores at 12 months. This will indicate whether there are any differences between the trial arms in addition to between the roles of Peer Navigator as opposed to Support Worker.

##### *2) Normalisation Measure Development Questionnaire (NoMad)*

The NoMad scores at baseline, 6, and 12 months will be downloaded from JISC into an Excel spreadsheet. Peer Navigators' and intervention staff's NoMad data will be analysed in terms of the frequency of responses to each item at baseline, 6, and 12 months. Responses to the NoMad will be used to understand the implementation of the Peer Navigator intervention in different intervention clusters.

### **4. Fidelity assessment**

#### Data collection and management

Peer Navigators will be asked each month to complete a content fidelity checklist based on the SHARPS intervention manual for each client they have had contact with each month (max n=300 checklists per Peer Navigator). This checklist assesses adherence to intervention content. Peer Navigators complete the checklists and email them each month to the research team. The role fidelity survey will be completed by the Peer Navigator's line manager at 6 and 12 months. The Enhancing Assessment of Common Therapeutic factors (ENACT) scale (8) was adapted to assess role

fidelity (with items 6,11, 14 and 18 removed due to irrelevance). Each item is scored on a 3-point Likert scale of (2) done well, (1) done partially, and (0) needs improvement. Finally, Peer Navigators are asked to keep a record of all the training they have completed during their time in the role in the training fidelity log.

### Data analysis

The latest version of SPSS available at the time of analysis will be used. The Peer Navigator fidelity checklist information will be entered into an Excel spreadsheet. The proportion of content checklists returned by each Peer Navigator will be calculated. Peer Navigator fidelity checklists will be analysed to assess which components of the SHARPS intervention were most commonly drawn on by the Peer Navigators, collectively. We will also assess whether there were any differences between Peer Navigators in terms of the components they drew on to deliver the SHARPS intervention to their clients, and whether there were any differences over time (i.e., whether the Peer Navigators used different components of the intervention at the beginning versus at the end of the 12-month intervention period). We will also use these checklists as a proxy to assess the number of clients the Peer Navigators engaged with each month during the intervention period as they are asked only to complete a checklist for each client they had contact with that month. The mean role fidelity score across all Peer Navigators will be calculated for 6 months and 12 months. Role fidelity scores will also be analysed both by comparing scores between Peer Navigators and within Peer Navigators (between the 6- and 12-month time point) to understand differences in the performance of Peer Navigators in their role from the perspective of their line manager.

Peer Navigator training logs will be assessed for completeness in terms of whether the training plan was followed by all Peer Navigators. Additionally, we will assess whether additional training opportunities differed for Peer Navigators between intervention clusters.

### **Dissemination and outputs**

As described in the study Publication and Dissemination Strategy, we will produce at least one paper of the process evaluation findings for publication in an academic journal, and some elements of the process evaluation may also be used in other publications. We will also share the findings via conference presentations, events/webinars, briefings, blogs, and press outputs.

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