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Assessing the impact of peer-led harm reduction on people experiencing homelessness and problem substance use: The SHARPS study

Submission date
03/04/2024

Recruitment status
No longer recruiting

Registration date
05/04/2024

Overall study status
Ongoing

Last Edited
23/06/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People who are experiencing homelessness tend to have poorer mental and physical health than people who are housed. They are also more likely to have problems with substances like alcohol and other drugs. Experiences of poverty and violence are some factors relating to future homelessness. Not everyone wants to reduce or stop using substances. Harm reduction aims to lower risks from substance use, without expecting people to stop and can improve access to essential services. People with experience of problem substance use, homelessness, and/or mental health problems, often called 'peers', can provide harm reduction interventions to people who are experiencing similar challenges, and have many benefits. These include building strong relationships and trust, improving mental health, and reducing risks from substance use. An earlier study called the SHARPS (Supporting Harm Reduction Through Peer Support; https://www.isrctn.com/ISRCTN15900054) feasibility study, based on six homelessness services in Scotland/England, examined if trained and paid peers, called Peer Navigators, could provide practical and emotional support to people who were experiencing homelessness and problem substance use (called participants). The study found that the Peer Navigators' lived experience meant they built trusting relationships quickly with participants, who often found it hard to trust other staff. They successfully connected them to wider support such as GPs, housing, and social care. This comprehensive trial, SHARPS-RCT, plans to test whether the relationships established with Peer Navigators can enhance the mental health and quality of life of participants, in contrast to individuals receiving similar services without Peer Navigators.

Who can participate?
Peer Navigators stationed in hostels and drop-in services operated by The Salvation Army and individuals experiencing homelessness and substance use issues from services in 20 cities and towns across England and Scotland

What does the study involve?
Services are expected to have an equal opportunity to either implement the 12-month SHARPS

intervention or provide the standard support available. Peer Navigators are anticipated to offer practical and emotional support to 25 clients for up to 12 months to facilitate positive changes in their lives and enhance their mental health and quality of life. A comparison of mental health and quality of life between services with Peer Navigators and those with standard support is expected to be conducted. Measurements of mental and physical health, quality of life, substance use, social support, and societal participation are planned at the study's onset, and again at 6, 12, and 15 months post-enrollment.

To gain insights into the intervention's practical implementation and wider contextual factors, a process evaluation is expected to be conducted. Interviews with participants who had Peer Navigators at the intervention's conclusion and three months thereafter, as well as Peer Navigators and select staff members, are planned. Additionally, a survey with staff/Peer Navigators and observations across all study services are expected to be undertaken. Individuals with lived experience are projected to have contributed to the creation of the SHARPS intervention and remain integral members of the study team. A UK-wide 'Experts by Experience' group is anticipated to guide the project.

To facilitate the dissemination and impact of findings, especially among stakeholders funding health and social care services, it is planned to widely share results through journal articles, conferences, social media platforms, a study website, blogs, and videos, and by organizing events in participating services.

What are the possible benefits and risks of participating?
People taking part in the study in intervention settings will benefit from the support received from the Peer Navigator. Working with the Peer Navigator for up to 12 months may help them to improve their physical and mental health, housing status, access to services (such as GP, dentist, optician), awareness of services and awareness of health conditions and how to manage them. As a thank you for taking part, all participants (those in the intervention and control arms) will receive a £25 voucher each time they complete the set of measures (four times in total) and will also be provided with refreshments while completing measures. Those participating in qualitative interviews will also receive a £25 voucher.

Participants might be asked questions they find difficult to answer or distressing. If this happens, the researcher and/or Peer Navigator (or other members of staff in services) will provide information to help them access appropriate support. Participants do not have to answer any questions they do not wish to answer.

Where is the study run from?
Salvation Army Centre for Addictions Services and Research, Faculty of Social Sciences, University of Stirling

When is the study starting and how long is it expected to run for?
January 2024 to March 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR)

Who is the main contact?
Prof. Tessa Parkes, t.s.parkes@stir.ac.uk

Study website
https://w3.abdn.ac.uk/hsru/SHARPS/Public/Public/index.cshtml

Contact information

Type(s)
Principal Investigator

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR150358

Study information

Scientific Title
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

Acronym
SHARPS-RCT

Study objectives
The SHARPS feasibility study showed that outcomes improved for those who received the intervention based on quantitative and qualitative evidence. There is considerable unmet need in this population and a lack of clear evidence regarding outcomes and cost effectiveness. This trial has been deemed necessary by the NIHR to be conducted to answer important research questions to support commissioning decisions in this area. The trial was a commissioned study at feasibility and full trial stage.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 24/01/2024, University of Stirling NHS, Invasive or Clinical Research Panel (NICR) (Cottrell 3B1, Stirling, FK9 4LA, United Kingdom; None available; ethics@stir.ac.uk), ref: NICR 2024 16751 12147

2. Approved 05/03/2024, Ethics Subgroup of the Research Coordinating Council of The Salvation Army (1 Champion Park, London, SE5 8JF, United Kingdom; None available; joyce.shaw@salvationarmy.org.uk), ref: SHARPS

Study design
Two-arm pragmatic cluster randomized controlled trial with cost-effectiveness evaluation and embedded mixed methods process evaluation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Charity/Voluntary sector

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Improvement of mental health and quality of life in people experiencing homelessness and problem substance use.

Interventions
The intervention that will be assessed is a relational, peer-delivered intervention for those experiencing homelessness and problem substance use. It was developed during the SHARPS feasibility study. At the core of this intervention is the provision of Peer Navigators (PNs) within The Salvation Army (TSA) homelessness services. The control group will receive standard care as provided by TSA's homelessness services.

Ten full-time PNs will be recruited and employed by TSA on 18-month contracts for 40 hours per week (i.e. one-month training, intervention for 12 months plus 1-month wind-down, additional 1-month recruitment period, and 3 months post-intervention work). All PNs will have lived experience of problem substance use and/or homelessness and are likely to have different experiences of recovery/harm reduction. PNs will be provided with the intervention guide which will provide them with the necessary information to carry out their role, including practical tools, anticipated challenges, and information about the needs of specific sub-populations.

Each PN will provide practical and emotional support to their 'caseload'. The caseloads have been determined using feasibility work and PPI feedback. Each PN will start with 25 clients, which it is anticipated might reduce to 17-20 clients throughout the intervention due to drop-

out. Practical support provided will likely encompass: healthcare; housing; benefits; help to access benefits; and setting up and advocacy within multi-agency appointments. Psychosocial and emotional support may include: listening; being consistent and reliable; helping to secure volunteering and employment opportunities; and helping to (re)connect with family and friends. A fund will also be available to the PNs to pay for travel, food, hot drinks, clothing, and phone calls, according to participant needs.

As part of their role, PNs will receive training (20 days at the start of their contract) on a range of topics including: harm reduction; psychologically informed environments and trauma-informed care; motivational interviewing; negotiating professional boundaries as peer workers; therapeutic relationships; and naloxone administration. Training will be provided by TSA and the Scottish Drugs Forum and use a revised version of the SHARPS intervention guide and training manual to support fidelity. Workplace supervision will be provided by TSA Service Managers who will line manage the PNs. This will be supplemented by monthly online reflective supervision sessions delivered by a trained peer worker and opportunities for the PNs to support each other.

Before the recruitment of PNs and participants, clusters (towns or cities in Scotland and England) will be randomised to the intervention or control group (1:1) using a computer-generated randomisation algorithm. Randomisation will be stratified by area-level deprivation, substance use, homelessness, and ethnicity characteristics, as well as TSA centre characteristics (e.g., number of centres, clients, and staff).

Participants must meet the inclusion criteria, however, the level and nature of problem substance use will vary between individuals. It is anticipated that, as with the feasibility work, most participants will be experiencing problem substance use that is severe and has an ongoing and substantial impact on their daily lives. Potential participants who are under the influence of alcohol/substances affecting their immediate ability to consent (but who do not have long-term /permanent cognitive impairment) will be re-approached to participate and consent one or two days later. Those who are under the influence will be mentioned to service management from the point of view of ensuring that they are provided with the appropriate support.

Intervention Type
Behavioural

Primary outcome measure
The co-primary outcomes are changes to mental health measured using the compositive Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS) and quality of life measured using the ICEpop CAPability Measure for Adults(ICECAP-A) both from baseline to 12 months

Secondary outcome measures
1. Changes to mental health measured using the Patient Health Questionnaire Anxiety and Depression (PHQ-ADS) andthe ICEpop CAPability Measure for Adults(ICECAP-A) at 6 and 15 months
2. Harmful substance use measured using the Maudsley Addiction Profile (MAP) and the Leeds Dependence Questionnaire (LDQ) at 6, 12 and 15 months
3. Risk-taking behaviours measured using the MAP at 6, 12 and 15 months
4. Social functioning including occupation/education roles measured using the MAP at 6, 12 and 15 months
5. Physical health measured using the MAP and European Quality of Life measured using the EuroQol health-related quality of life measure (EQ-5D-5L) at 6, 12 and 15 months
6. Course of homelessness measured using RAND at 6, 12 and 15 months

7. Social outcomes, therapeutic alliance with PN and support workers, and service accessibility measured using items fromthe Social Satisfaction Questionnaire (SSQ) and the Interpersonal Support Evaluation List (ISEL) 12-item version at 6, 12 and 15 months
8. Service utilisation measured using MAP, self-report hospitalisations and items fromthe Client Evaluation of Self and Treatment (CEST) at 6, 12 and 15 months
9. Relational empathy measured using the Consultation and Relational Empathy measure (CARE at 6, 12 and 15 months

Overall study start date
07/01/2024

Completion date
31/03/2027

Eligibility

Key inclusion criteria
1. >18 years and experiencing/at risk of homelessness (ETHOS definition)
2. Self-report problem substance use (using pre-determined scoring 'cut off')
3. Able to provide informed consent.

Participant type(s)
Service user

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
550

Total final enrolment
466

Key exclusion criteria
Current exclusion criteria as of 24/10/2024:
1. Current participation in other alcohol and/or substance use intervention trials
2. Inability to give clear informed consent due to serious mental illness or cognitive impairment or posing a safety risk to staff members/PN or individuals who are actively disclosing suicidal intent
3. Non-English speaking (due to the intervention involving Peer Navigator relationship and they will not necessarily have languages other than English).

Previous exclusion criteria:
1. Current participation in other alcohol and/or substance use intervention trials
2. Inability to give clear informed consent due to serious mental illness or cognitive impairment or posing a safety risk to staff members/PN
3. Non-English speaking (due to the intervention involving Peer Navigator relationship and they will not necessarily have languages other than English).

Date of first enrolment
30/07/2024

Date of final enrolment
06/06/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
The Salvation Army, James Lee House Lifehouse
Brick Street
Warrington
United Kingdom
WA1 2PD

Study participating centre
The Salvation Army, Willow House
Willow Street
Reading
United Kingdom
RG1 6AB

Study participating centre
The Salvation Army, Shepton House
South Street
Reading
United Kingdom
RG1 4QT

Study participating centre
The Salvation Army, Booth Lifehouse
1-3 Eleanor Street
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Organisation
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Sponsor type
University/education

Website
https://www.stir.ac.uk/

ROR
https://ror.org/045wgfr59

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Our dissemination/pathways to impact strategy will be developed with input from a range of statutory and non-statutory health/social care stakeholders that commission and provide relevant services, including our Experts by Experience Group and Trial Steering Group. A range of outputs will be disseminated with details provided below:

1. Public dissemination: We will share findings with trial participants in line with current HRA guidelines (https://www.hra.nhs.uk/planning-andimproving-research/best-practice/publication-and-dissemination-research-findings/). We will also use Comms expertise within Stirling and Aberdeen Universities to alert the popular press about the trial. A trial website and X/Twitter account will be used to promote study progress and publications. We will prioritise plain English summaries and the creation of accessible study information using infographics, videos, and use social media outlets such as X/Twitter to share these. We will work with the Peer Navigators and Experts by Experience group to create a toolkit of blogs and videos to 'bring the project to life'. Findings will be shared with participants in a way deemed most suitable.

2. Conferences: National and international conferences and meetings/events (online/in person) will target key stakeholders such as health and social care commissioners, service providers, advocacy/third sector groups, citizen groups, and interested individuals. We will follow up with stakeholders after conferences and events to enable evaluation of intervention uptake (post-trial) in other settings.

3. Publications: We will focus on high-impact journals with linked mainstream publicity (via press releases). These papers will include the protocol and main findings of the study, plus manuscripts on methodological areas of interest such as recruiting and retaining people experiencing homelessness. They will be published open access in high-profile, international journals (such as Addiction, BMC Open, BMC Public Health).

4. Roadshow: We will organise a findings 'roadshow' to engage diverse stakeholder groups across the UK and share creative study materials.

5. Policy makers/commissioners: We will share findings with relevant policy makers /commissioners at local/national Government level (and internationally as required), and input into relevant clinical guidelines (e.g., NICE/SIGN), via bespoke briefings, meetings and events using our extensive networks.

Intention to publish date
31/03/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Tessa Parkes, t.s.parkes@stir.ac.uk. We will ask intervention and control participants if they consent to share their anonymised data with other researchers in the form of the final quantitative dataset. We have to balance the need to ensure recruitment targets are met with this desire to comply with best practices in the field. if client participants are not comfortable with sharing their data, we will revise our plan to do this because it is more important to be sensitive to the needs of this client group and their concerns than to meet open science obligations given the client group is likely to have had experiences that may make them suspicious of data sharing, despite the commitment to fully anonymising the dataset. We will provide a box on the consent form which indicates that sharing their details via open science will be optional and then the research team will make a decision about proceeding with the possibility of the open science dataset being shared once all participants are recruited. The dataset will only be shared if all participants agree. We will not be sharing the qualitative datasets due to potential small numbers and challenges anonymising the data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 1	24/07/2024	14/08/2024	No	No