

Supporting Harm Reduction through Peer Support

Submission date 28/03/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/03/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/04/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

People who are homeless have worse physical and mental health, and higher rates of substance use (alcohol or drugs), than the general population. For some people with severe substance use problems, completely stopping their use is a complex challenge. Many people who end up being homeless have had very difficult lives including traumatic experiences. Harm reduction services can be useful in cutting the risks connected with substance use, for example needle exchange services. Harm reduction aims to support people 'where they are at', rather than trying to get people to change before they are ready or able to do so. Harm reduction supports people to improve their quality of life. While harm reduction is suggested for homeless people there is a lack of research on exactly how it should be delivered. This study will build on research that has already been done to show that trusting relationships with staff can help people with serious health and social problems. Homeless people need services that suit their specific needs, with staff that are good listeners, caring and understanding. Relationships seem to be most helpful when staff also offer practical help. This study will involve peer 'Navigators' providing practical and emotional support to homeless people who have substance use problems. Peers are people with personal experience of problem substance use who are recovering and have been trained in a range of areas. The word 'Navigator' is used to mean that these workers will closely support each person. The aim of this study is to explore whether the Peer Navigator programme can be delivered to people with serious problem substance use in hostel and outreach settings for homeless people.

Who can participate?

People who are homeless or at risk of becoming homeless, who have alcohol or drug problems

What does the study involve?

The Peer Navigators build trusting relationships to try to help each person improve their quality of life and their health in a safe and supportive environment. As part of the study, a 'whole person' health check is offered and completed by a study researcher. Checks like this can take a while and can be off-putting so it is offered once a trusting relationship has been developed and when the person is comfortable with it. The Peer Navigators then help the person to find services that can meet their needs, such as healthcare, housing or counselling. They also go with them to appointments if needed. The practical support offered includes having enough money

to travel to appointments and to buy basics such as hot drinks, food and bus fares. The study looks at whether people want to get involved with the Navigators or not. It looks at how the Peer Navigators and participants work together. It also asks staff how they felt about delivering the programme. It does not find out if the programme actually improves people's lives as that is something that would happen in a later study. To understand how the programme works, Peer Researchers do interviews with a group of the participants at two different points in time. Interviews are also done with the Peer Navigators and other staff members working in the homeless services. Peer Researchers are also involved in making sense of the research findings alongside the research team. People with lived experience have been involved in the design of the Peer Navigator programme and the research study. The most important outcome of the research would be to decide if further research should be carried out to see if the Peer Navigators make a real difference to people's lives and to their health.

What are the possible benefits and risks of participating?

It is hoped that people taking part in the study will benefit from the support received from the Peer Navigator. Working with the Peer Navigator for up to 12 months may lead to improvements in: physical and mental health; housing status; access to services (such as GP, dentist, optician); awareness of services; and awareness of particular health conditions and how to manage them. It cannot be guaranteed that participants will experience any or all of these, but it is hoped that working with the Peer Navigator will be beneficial for those involved. It is hoped that participation in the study will not cause participants any harm. During the health check, participants will only have to answer questions and no tests (such as bloods) will be carried out. Participants might be asked questions they find difficult to answer or distressing. If this happens, the Peer Navigator will ensure participants have access to appropriate support so they can deal with this distress in a supportive manner. Participants will be informed that they do not have to answer any questions they do not wish to answer.

Where is the study run from?

1. Streetwork (UK)
2. Pre-Sync 27, Recovery Hub (Cyrenians) (UK)
3. Niddry Street drop in (Salvation Army) (UK)
4. Darbyshire House Lifehouse (Salvation Army) (UK)
5. Ann Fowler House Lifehouse (Salvation Army) (UK)
6. The Orchard Lifehouse (Salvation Army) (UK)

When is the study starting and how long is it expected to run for?

May 2018 to April 2020

Who is funding the study?

NIHR Health Technology Assessment Programme (UK)

Who is the main contact?

Dr Tessa Parkes

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Contact information

Type(s)

Public

Contact name

Dr Tessa Parkes

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 16/153/14

Study information

Scientific Title

Testing the feasibility and acceptability of a peer-delivered, relational intervention for people with problem substance use who are homeless, to improve health outcomes, quality of life and social functioning, and reduce harms

Acronym

SHARPS-feasibility

Study objectives

This study will develop and test the use of a peer-to-peer (using Peer 'Navigators') relational intervention. Drawing on the concept of psychologically informed environments it will focus, first and foremost, on providing trusting and supportive relationships. This feasibility study aims to: develop and implement a non-randomised, peer-delivered, relational intervention, drawing on principles of psychologically informed environments, that aims to reduce harms and improve health/wellbeing, quality of life, and social functioning, for people who are homeless with problem substance use; and conduct a concurrent process evaluation, in preparation for a potential randomised controlled trial, to assess all procedures for their acceptability, and analyse important intervention requirements such as fidelity, rate of recruitment and retention of participants, appropriate sample size and potential follow-up rates, the 'fit' with chosen settings and target population, availability and quality of data, and suitability of outcome measures.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 27/04/2018, NICR (University of Stirling), ref: NICR 17/18 Paper 35. Amendments approved 06/11/2018, 22/11/2018, 13/02/2019, 26/05/2019.
2. Approved 05/06/2018, Salvation Army ethics committee, ref: none. Amendments approved 20/11/2018, 23/11/2018, 12/02/2019, 04/06/2019.

Study design

Mixed-method feasibility study with concurrent process evaluation

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Problem drug/alcohol use and homelessness

Interventions

Intervention as of 14/12/2018:

The study will involve peer 'Navigators' providing practical and emotional support to homeless people who have substance use problems. Peers are people with personal experience of problem substance use who are recovering and have been trained in a range of areas. The word 'Navigator' is used to mean that these workers will closely support each person. The Peer Navigators will build trusting relationships to try to help each person improve their quality of life and their health in a safe and supportive environment. As part of the study, a 'whole person' health check will be offered and completed by a study researcher. Checks like this can take a while and can be off-putting so we will make sure that it is offered once a trusting relationship has been developed and when the person is comfortable with it. The Peer Navigators will then help the person to find services that can meet their needs, such as healthcare, housing or counselling. They will also go with them to appointments if needed. The practical support offered will include having enough money to travel to appointments and to buy basics such as hot drinks, food and bus fares.

The aim is to explore whether the Peer Navigator programme can be delivered to people with serious problem substance use in hostel and outreach settings for homeless people. The study will look at whether people want to get involved with the Navigators or not. It will describe how the Peer Navigators and participants worked together. It will also ask staff how they felt about delivering the programme. It will not find out if the programme actually improves people's lives as that is something that would happen in a later study. To understand how the programme works, Peer Researchers will do interviews with a group of the participants at two different

points in time. Interviews will also be done with the Peer Navigators and other staff members working in the homeless services. Peer Researchers will also be involved in making sense of the research findings alongside the research team. People with lived experience have been involved in the design of the Peer Navigator programme and the research study. The most important outcome of the research would be to decide if further research should be carried out to see if the Peer Navigators make a real difference to people's lives and to their health.

The total duration of the intervention is up to 12 months. There is no additional follow up for participants due to the study being a feasibility study rather than an outcome trial.

Previous Intervention:

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The total duration of the intervention is 12 months. There is no additional follow up for participants due to the study being a feasibility study rather than an outcome trial.

Intervention Type

Other

Primary outcome measure

Primary outcome measure as of 14/12/2018:

1. Estimates of recruitment and retention of participants
2. Participant engagement with the intervention and acceptability of intervention to participants /staff

3. Time needed to collect/analyse data
4. Sample size estimates
5. Fidelity

The specific outcome measures that will be tested for use in a trial are:

1. Standardised measures of socio-demographic characteristics
2. Housing status/quality, measured using MAP
3. Quality of life, measured using SF36
4. Substance use, measured using SURE
5. Mental health, measured using GAD7 and PHQ9
6. Relationship quality, measured using CARE

These measures will be used during holistic health checks when the participant is ready for these to be completed. Therefore, there are no specific timepoints.

Previous Primary outcome measure:

1. Estimates of recruitment and retention of participants
2. Participant engagement with the intervention and acceptability of intervention to participants /staff
3. Time needed to collect/analyse data
4. Sample size estimates
5. Fidelity

The specific outcome measures that will be tested for use in a trial are:

1. Standardised measures of socio-demographic characteristics
2. Housing status/quality, measured using MAP
3. Quality of life, measured using EQ-5D-5L
4. Substance use, measured using SURE
5. Mental health, measured using HADS
6. Relationship quality, measured using CARE

These measures will be used during holistic health checks when the participant is ready for these to be completed. Therefore, there are no specific timepoints.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/05/2018

Completion date

30/04/2020

Eligibility

Key inclusion criteria

1. People who are homeless/at risk of becoming homeless
2. Self-reported alcohol or drug problems

Participant type(s)

Other

Age group

Adult

Sex

Both

Target number of participants

60

Total final enrolment

68

Key exclusion criteria

1. Those unable to provide informed consent
2. Aged under 18
3. Those who do not use alcohol or drugs
4. Those who do not self-identify as using substances

Date of first enrolment

01/10/2018

Date of final enrolment

12/04/2019

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre

Streetwork

18 South Bridge

Edinburgh

United Kingdom

EH1 1LL

Study participating centre

Pre-Sync 27, Recovery Hub (Cyrenians)

27 George Street

Bathgate

United Kingdom

EH48 3JQ

Study participating centre
Niddry Street drop in (Salvation Army)
25 Niddry Street
Edinburgh
United Kingdom
EH1 1LG

Study participating centre
Darbyshire House Lifehouse (Salvation Army)
380 Prescott Road
Liverpool
United Kingdom
L13 3DA

Study participating centre
Ann Fowler House Lifehouse (Salvation Army)
45 London Road
Liverpool
United Kingdom
L3 8HY

Study participating centre
The Orchard Lifehouse (Salvation Army)
371 Leeds Road
Bradford
United Kingdom
BD3 9NG

Sponsor information

Organisation
University of Stirling

Sponsor details
Research and Innovation Services
Stirling
Scotland
United Kingdom
FK9 4LA

Sponsor type

University/education

ROR

<https://ror.org/045wgfr59>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The protocol will be made available via the NIHR. Phase 3 will involve the dissemination of study findings to a wide range of audiences. The PPI and Study Steering Groups will advise on a dissemination strategy to ensure that findings are easy to understand and are disseminated in routes that are accessible to a wide range of audiences. The trialists will follow the 26 item CONSORT checklist for reporting feasibility studies in our outputs which will include the following:

1. A final study report to NIHR and, if findings and Steering Group recommend it, a proposal for a full trial
- 2 Revised, finalised intervention manual for effectiveness testing in a full trial
3. Revised, finalised training manual for the Peer Navigators, to inform a full trial
4. At least two academic manuscripts will be written for open access publication in relevant and high impact peer reviewed journals such as Addiction, Drug and Alcohol Review, European Journal of Homelessness
5. Ongoing 'blog' posts on the study via the Salvation Army Centre website and social media postings using Twitter

6. A paper on the use of Peer Researchers written with the Peer Researchers as lead authors
7. A short briefing paper made available for practitioners, policy makers and other stakeholders, available via the Centre for Addiction Services and Research website on the feasibility work

Intention to publish date

01/07/2021

Individual participant data (IPD) sharing plan

Due to the study being a feasibility and acceptability trial involving a process evaluation, participant data will not be available. If a future trial is commissioned the trialists would supply participant data at that stage.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/04/2019	15/01/2021	Yes	No
Other publications	commentary article on experiences in a Patient and Public Involvement group	20/11/2021	26/01/2022	Yes	No
Results article		04/02/2022	07/02/2022	Yes	No
Results article	HTA	01/02/2022	28/02/2022	Yes	No