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Supporting harm reduction through peer support (SHARPS): 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.

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The purpose of this protocol is to describe the study and provide information about the procedures for entering participants into the study. Every care has been taken in drafting this protocol however corrections or amendments might be necessary.

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Keywords

Harm reduction, substance use, peer navigators, homelessness, feasibility trial

1. Summary of Research

Background
People who are homeless often experience poor mental and physical health and problem substance use (1), but getting access to appropriate services can be challenging (2). Enabling the development of trusting relationships with non-judgemental staff can facilitate initial and continued engagement (3); with peer-delivered approaches being particularly helpful (4). 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 (5,6). Navigator is a term used for a worker who supports people through service systems (7), with such roles starting to be used in hospital and housing services in various parts of the UK. Peer is a term used to describe people with lived experience of problem substance use and/or homelessness whose lives are now stable.

Research questions:

1. Is a peer-delivered, relational harm reduction approach accessible and acceptable to, and feasible for, people who are homeless with problem substance use in non-NHS settings?
2. If so, what adaptations, if any, would be required to facilitate adoption in wider NHS and social care statutory services?
3. What outcome measures are most relevant and suitable to assess the effect of this intervention in a full randomised controlled trial (RCT)?
4. Are participants and staff/service settings involved in the intervention willing to be randomised?
5. On the basis of study findings, is a full RCT merited to test the effectiveness of the intervention?

Aims
This feasibility study aims to:

1. 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;

2. 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.

Design
A mixed-method feasibility study with concurrent process evaluation to explore the feasibility and acceptability of a peer-delivered, relational intervention for people with problem substance use who are homeless.

Settings
Three outreach services for people who are homeless in Scotland, and three Salvation Army hostels in England.

Difference between current/planned care pathways
Two standard care settings have been selected that are similar to the intervention sites in key ways but will not have a Peer Navigator located within them.

Target population and inclusion/exclusion criteria
People who are homeless/at risk of homelessness with problem substance use and unlikely to achieve abstinence. Inclusion: people who are homeless and self-report alcohol or drug problems. Exclusion: those unable to provide informed consent, those under 18, those who do not use alcohol or drugs, those who do not self-identify as using substances.

Health technologies being assessed

Peer-delivered relational intervention drawing on principles of psychologically informed environments, providing practical and emotional support. A holistic health check using standardised measures will also be conducted by researchers (Carver/Foster) to gain an understanding of participants' physical and mental health needs.

Sample size

We aim to recruit 60 people to the intervention with four Peer Navigators. Some attrition will be expected and monitored. In the event that there are more than 60 people who wish to take part, a waiting list will be kept so that if a participant drops out a new person can be engaged (up to a specified time point, likely March 2019, to allow at least six months for engagement due to the relational nature of the intervention). For the concurrent process evaluation, a purposive sample of 20-25 participants (approximately one third of the total sample of 60) will be identified for qualitative interviews at two different time-points in order to assess changes in perception of the intervention over the period. Follow up interviews (n=10) will also be attempted with a sample of participants who drop out using criterion sampling (8). The holistic health checks that are undertaken with participants as an integral part of the intervention will also provide data regarding their suitability of use as outcome measures for a future trial. All participants who consent to these checks will be asked if they consent to these data being used for the evaluation. These checks will be completed by a researcher (Carver/Foster), with the support of the Peer Navigator, if required by a participant. Qualitative interviews will be conducted with a purposive sample of 16 staff members across the settings where the Peer Navigators are based and the standard care settings. Qualitative interviews will be undertaken with all four Peer Navigators at three time points to assess changes in perception and practice through the intervention period.

Methods

The health technology being assessed is a peer-delivered (using Peer Navigators), relational intervention for people who are homeless, or at risk of becoming homeless, with problem substance use. They will build trusting relationships and offer practical and emotional support to help each person who engages to stabilise their lives. As part of the intervention, a holistic health check will be offered twice throughout the intervention, once towards the beginning and the second near the end and undertaken by a researcher (Carver/Foster). These checks will include; standardised measures of socio-demographic characteristics, housing status/quality and general health status; quality of life (SF36); substance use (SURE and MAP); mental health (GAD7/PHQ9); and relationship quality (CARE). The suitability of these measures with the target population will be assessed. The intervention will be delivered in six settings: three outreach settings in Scotland and three inner-city hostels in the North of England. Two services have been identified as standard care settings and staff in these sites will also use the measures with a sample of their residents/service users. As a feasibility study we will conduct a concurrent process evaluation, informed by Normalisation Process Theory (9), in preparation for a full trial to assess all procedures for their acceptability and analyse important intervention requirements such as fidelity, rate of recruitment and retention, adequate samples sizes, 'fit' with context and target population, availability and quality of data, the ethics/equipoise of the intervention, and the suitability of the outcome measures. Data collection for the process evaluation will be quantitative, using the socio-demographic information and health check measures above, and qualitative, using semi-structured interviews with participants, Peer Navigators, staff in service and standard care settings, and non-participant observations in the intervention and standard care sites. Data analysis will focus on how staff adopt/perceive the intervention, how those receiving it engage, and other contextual factors impacting delivery.

Outcomes and outputs

Primary outcomes will be estimates of recruitment and retention of participants; assessment of participant engagement with the intervention and acceptability of intervention to participants /staff; time needed to collect/analyse data; sample size estimates; and fidelity, in order to fully inform a future trial. The specific outcome measures that will be tested for use in a trial are noted above. Using the study findings we will produce a refined intervention manual/staff training resource, a final report that addresses the research questions, and associated academic manuscripts.

2. Background and Rationale for Study

The proposed research addresses the NIHR commissioning brief that sets out the need for a study on harm reduction and homelessness to be done as soon as is practicable. Homelessness is a complex and multi-faceted issue involving deep social exclusion (10). It is also frequently characterised by 'tri-morbidity,' a term coined to describe those impacted by both poor mental and physical health who also have problem substance use (1). Problem substance use is often a factor contributing to someone becoming homeless. It is common for people to start using substances after being homeless, with 54% trying heroin, 72% crack, 70% benzodiazepines, and 12% alcohol (11); 77% report smoking (12). Rates of use can increase as a way of coping (13). People who are homeless often report far worse physical and mental health than the general population, with greater incidences of injury, assault, infectious diseases, skin conditions, chronic health problems, nutritional deficiencies, problem substance use and mental illness (14–16). A recent study showed rates of ill-health comparable to those aged over 85 years in the general population (17). People who are homeless are also four times more likely to die prematurely than the general population, with the average age of death being 37 years for women and 42 years for men, compared with 54 and 51 years in the wider population of problem drug users respectively (18).

Homelessness has been viewed as an issue connected primarily to social care and a lack of housing, with too little focus on the significant connections to health and wellbeing (1). Despite many people who are homeless being registered with a GP, a significant number of people report that they are not receiving help with their health problems (12). This has meant that those who are homeless often access healthcare services at a crisis point, utilising accident and emergency services rather than primary care (1,17,19,20), with high cost implications for the NHS (1). Their use of such services is four times higher than the general population, costing an estimated £85 million per year (12). There is also evidence that when people who experience homelessness do access mainstream healthcare or substance use services, their needs are not well met: they can experience stigma and negative attitudes from staff, be viewed as second class citizens, and encounter inflexible services (19–22).

In terms of problem substance use, there are two main approaches to service provision: those aimed at helping people achieve abstinence and those that use a harm reduction model (23). There is debate regarding whether or not abstinence-focused interventions are effective and appropriate for this group of people with such complex needs (3). While such interventions can be effective, they rely on people who are homeless accessing services, which can be difficult. Unstable living conditions can mean that treatment appointments are missed, and plans and regimes difficult to maintain (19). For some people experiencing homelessness who use alcohol and drugs, abstinence is unlikely to be achieved, so approaches are required that reduce the harms associated with use (23–25). Since use of both alcohol and drugs is common, it has been suggested that harm reduction approaches should address both or all substances (24). Harm reduction aims to support people 'where they are at', rather than seeking particular treatment goals (26), thus facilitating autonomy. Importance is placed on the service user exercising choice to set goals and people are not forced to be abstinent (26–28). Collins et al. have discussed the importance of 'grass roots' as well as 'top down' harm reduction (29) which acknowledges the important differences between approaches that come directly from advocacy and mutual aid groups, like peer-organisations, rather than public health organisations. Despite this current literature, there is limited evidence regarding how harm reduction should be delivered to those who experience homelessness.

While interventions to improve the health of people who are homeless have received increased attention in the last decade (30), when reviewing literature to inform our response to the commissioning brief we found no relevant Cochrane Reviews. After searching relevant databases, several systematic reviews were identified which examined the effectiveness of interventions to improve health and problem substance use outcomes for those who are homeless. These reviews conclude that having primary care services tailored to those experiencing homelessness (3), case management (14,30,31), and provision of housing (30), can be effective in improving mental and physical health and address problem substance use. The Centre for Addiction Services and Research at Stirling is funded by the Salvation Army to conduct systematic reviews and meta-ethnographies relevant to their work, particularly on the intersecting issues of health, homelessness and substance use. We (Parkes, Carver) are conducting a meta-ethnography (completion November2018) on the views of people with problem substance use who are homeless on effective components of substance use treatment, which aims to partly address this gap.

In terms of problem drug use more broadly, there is a considerable body of evidence on the effectiveness of opioid replacement treatment, particularly relating to the prevention of drug-related deaths (32). Opioid-related deaths are a particular risk for those not in contact with drug services, many of whom are homeless (32). Needle exchange programmes aim to reduce the harms associated with injecting drugs, such as blood borne viruses and bacterial infections, as well as offering advice on minimising the harms associated with drug use, and access to treatment and other health and welfare services (33). There is evidence that needle and syringe programmes can reduce both injecting and HIV risk behaviours but be part of a wider harm reduction programme (34). The effectiveness of such programmes to both reach and then stay in contact with highly marginalised populations has been widely documented (35,36). Harm reduction services can act as a 'gateway' to other services, including to health and housing, and substance use treatment (37,38). There is thus a need for a range of approaches for those not in treatment who are vulnerable to drug-related deaths, such as people who are homeless, including provision of naloxone, heroin assisted treatment, drug consumption rooms, and assertive outreach services (32).

For alcohol use, screening and brief interventions are the most common evidence-based approaches used for the general population, although they tend to be more appropriate and effective for harmful and hazardous drinkers rather than those with severe dependence (39), and there is a lack of evidence regarding use with people who are homeless (39). There is evidence, however, that occasional detoxification and provision of medical support can improve health outcomes for street drinkers who are homeless but with the expectation that long-term abstinence is unlikely to be achieved (25). Managed alcohol programmes (MAPs) provide regulated amounts of alcohol, as well as housing and other support, as way of managing severe alcohol dependence in people who are homeless and with the aim of proactively addressing both homelessness and alcohol use (40). MAPs are prevalent in Canada, primarily in the provinces of British Columbia and Ottawa. While a recent systematic review of these programmes was unable to identify suitable studies for inclusion due to non-experimental study designs (41), there is evidence from small-scale studies showing reductions in emergency room visits, police encounters and alcohol-related harms; improved quality of life, wellbeing and mental health; retention in housing; and increased safety (40,42,43). MAPs thus show much promise for this group of people.

In terms of the wider evidence-base, studies have highlighted a number of effective components of harm reduction services. The building of trusting relationships with staff in services is key, as is the importance of service user-directed goals, and being accepted as a person (27,40). Within harm reduction services, ongoing substance use and relapse are viewed as natural and met with a non-judgemental response to continue to facilitate trusting, supportive relationships (27). Services that are accessible, with staff who are good listeners and have caring, non-judgemental attitudes, can facilitate engagement with a range of groups that can be reluctant to engage with mainstream services (44,45). A number of studies have pointed to a very basic but essential point: people should be treated like human beings with worth (26,40) which is not what this group of vulnerable people necessarily experience when they use health, substance use or social services (46,47).

The development of trusting, consistent and reliable relationships is also essential for those experiencing homelessness (26,28,40,48,49). Neale and Stevenson interviewed people who are homeless with drug and alcohol problems living in hostels to examine the nature and extent of their social and recovery capital (50). Participants viewed supportive relationships with professionals as critical to their wellbeing and future outcomes. Hostel staff were noted as going 'above and beyond' what was expected from them: being caring and responsive to needs, and protecting people (50). Developing good relationships between healthcare professionals and those who are homeless has also been found to be especially important for engagement, particularly when dealing with those with substance use issues and other health problems (3,4). Mills et al. interviewed staff working in homelessness primary care services in the UK and found that the development of trusting relationships, and listening to people well, was crucial to engagement of people experiencing homelessness in services (21). Importantly, when people who are homeless developed good relationships with healthcare professionals they would bring friends with them, thus extending reach (21). Pauly has also highlighted the importance of trusting relationships as essential to access to primary care in Canada (51). This literature has much in common with research on effective approaches for those experiencing homelessness and mental health problems: flexible services; good relationships with professionals; care based on mutual communication and advocacy; practical support; and having workers with lived experience (52). Services viewed as 'unhelpful' had staff who were judgemental, lacking compassion and 'clinically detached' and used medical

models of care that expected people to be grateful for help. Refusing to give support because of substance use also featured (52).

These findings relate to literature on psychologically informed environments, a recent development in homelessness settings which uses a psychological framework to develop services for people with complex histories to enable *'the best chance of sustainably escaping the cycle of poor wellbeing and chronic homelessness'* (53, p.4). As well as having an explicitly relational focus, working actively with a person's experiences of trauma, and ensuing emotional impact, lie at the core of the approach (6). The coping strategies people develop, including substance use, are understood in this context. Psychologically informed environments aim to help people to make changes to behaviours on their own terms using supportive relationships (6).

It is also critically important to acknowledge the vital contribution made by those with lived experience to relational interventions in the housing and health fields. Peer support workers have been used in mental health settings and there is evidence that they can improve outcomes for those using services, particularly in terms of giving hope, facilitating empowerment and self-esteem (54). In terms of substance use, peer-based harm reduction services, such as the provision of safer injection advice, can facilitate engagement and reduce drug-related deaths (15,38) through the development of trusting relationships (55–57). Peer-delivered interventions have also been found to be effective, compared to more traditional outreach interventions, in reducing the risks associated with injecting drug use. Broadhead et al. compared a peer-led HIV intervention with a traditional outreach intervention and found that having peers with experience of injecting drug use resulted in the recruitment of a greater number of service users and reductions in risky injecting behaviour (58). Similarly, Latkin et al. found that a peer-delivered intervention resulted in reductions in drug use, needle sharing and using unclean needles (59). Peer support roles have also been used in homelessness settings in the UK (Cyrenians, St Mungo's, Shelter, and Groundswell), although evaluation is sparse (60). O'Campo et al. examined the literature on community-based services for people who are homeless experiencing mental health and substance use problems and found that in one programme peer support staff were particularly effective in developing good relationships with service users (4). Research indicates that while peer workers benefit from their role in terms of increased confidence and self-esteem, and as a way of reintegrating into the community (55), there can also be challenges. Effective training, supervision and management, clear role descriptions, and acceptable pay, are all important in addressing such challenges (54,55,61). Broadhead et al., for example, recognise the potential for relapse for workers when engaging with those still using substances, and suggest the provision of good supportive 'clinical' supervision and opportunities for working in pairs (58).

Taken together, these studies highlight the importance of particular components of harm reduction that can contribute to engaging well with people who can easily become marginalised within mainstream health, social and housing services. The critical component to both good engagement, and then progress on self-identified life goals, is the facilitation of a trusting, supportive relationship. Non-judgemental attitudes are absolutely vital in engaging people with complex needs in healthcare, including those with problem alcohol and drug use who are also homeless. While there is considerable evidence regarding harm reduction approaches more generally, evidence is lacking for approaches that are both acceptable to, and effective with, people who are homeless who use both drugs and alcohol. As noted in the commissioning brief, this leaves a substantial gap in knowledge for those working in the health, social and housing sectors trying to meet this population's needs.

The proposed study aims to add to this body of knowledge, by combining some of the most effective components of harm reduction and peer delivery noted above. It will provide an explicitly relational intervention aimed at engaging with, and then actively supporting, people who are homeless to address a range of health and social issues on their own terms. It will examine whether it is feasible to deliver a peer-to-peer intervention based on psychologically informed environments that provides practical and emotional support for people experiencing homelessness and problem substance use in non-NHS settings. Holistic health checks using standardised measures of physical and mental health will also be conducted by researchers (Carver/Foster). It will assess the acceptability of the intervention, its ability to access and engage people, and appraise a range of critical intervention requirements that would need to be fully understood before proceeding to a future trial.

A study published in June 2017 in Scotland recommended health assessments for older people with problem drug use due to the multiple morbidities they experience. Many were living in temporary accommodation and

91% had experienced past homelessness (62). Modelling work undertaken by the NHS's Information Services Division as part of the study estimated that the number of older people with drug problems will continue to increase for a period of years, before stabilising, suggesting a pressing need to work more proactively and effectively with this group of vulnerable people (62). Trying to respond effectively to the many health problems connected to a person's experience of homelessness, and their wider life experiences, is therefore a public health priority. Alongside trying to deal with the causes of homelessness, including poverty, social inequalities, unemployment and relationship breakdown, effective healthcare interventions are also needed to address the intersecting health and social problems experienced by this group, reduce harms, and enhance their quality of life, relationships and social functioning. The target population are often users of hospital services in crisis situations (20), yet their health needs can be more appropriately managed in community settings, prior to crisis (3). As detailed in section 3, there is now a developing evidence base showing that harm reduction, and other targeted interventions for people who are homeless and use substances, can also have wider societal benefits. For example, hospital and emergency services often struggle to cope with the complex needs of this population (63) and early evidence suggests that targeted harm reduction services are able to reduce the number of visits to emergency departments (1,3,15) thus reducing strain on healthcare and other public services (40,42).

As we have outlined above, relational and peer-led harm reduction approaches show much promise in engaging, and then effectively working with, people with intersecting housing, health and alcohol and drug use challenges; to reduce harms and enhance physical and mental health and wellbeing, quality of life, social functioning and relationships. While there is evidence that both the relational 'therapeutic alliance' and the peer-led approach can be powerful tools for this vulnerable population, our literature searching has identified that much more rigorous investigation is required as evidence to date is based on small scale pilot studies. We are excited about the potential of contributing to this evidence base which could not be more timely. Our proposed study would make a significant and original contribution to the international and national evidence that decision makers and those in practice need, and will value.

3. Research questions, aims and objectives

Informed by this evidence base, our research aims to develop, implement and evaluate key features of a peer-delivered, relational intervention drawing on psychologically informed environments. While the intervention aims to reduce harms and improve the health and wellbeing, quality of life, and social functioning for those who participate, as a non-randomised feasibility study it will not assess effectiveness of the intervention.

Research questions:

1. Is a peer-delivered, relational harm reduction approach accessible and acceptable to, and feasible for, people who are homeless with problem substance use in non-NHS settings?
2. If so, what adaptations, if any, would be required to facilitate adoption in wider NHS and social care statutory services?
3. What outcome measures are most relevant and suitable to assess the effect of this intervention in a full randomised controlled trial (RCT)?
4. Are participants/staff/service settings involved in the intervention willing to be randomised in a RCT?
5. On the basis of study findings, is a full RCT merited to test the effectiveness of the intervention?

Aims: This feasibility study aims to:

1. 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 in non-NHS settings;
2. conduct a concurrent process evaluation, in preparation for a RCT, 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.

Objectives: Our research objectives are to:

1. fully develop the proposed intervention using co-production for use in community outreach/hostel settings with applicability to wider settings including the NHS (Phase 1);
2. create a manual to guide the intervention and an associated staff training manual (Phase 1);
3. test the feasibility of recruiting to the intervention, and measure rate of recruitment/attrition in order to determine appropriate sample size and follow up rates for a full RCT (Phases 2, 3);
4. deliver a non-randomised, peer-delivered, relational intervention based on principles of psychologically informed environments, with integral holistic health checks (conducted by researchers Carver/Foster) based on already identified outcome measures (Phase 2);
5. assess the acceptability and feasibility of all procedures in the intervention using Normalisation Process Theory, including staff and participant perceptions of its value, strengths and challenges (Phases 2, 3);
6. assess the acceptability of the holistic health checks, and all identified outcome measures, to determine the best way to measure outcomes for this particular intervention and population in a future randomised trial (Phases 2, 3);
7. assess fidelity, adherence to manual, 'fit' to context, and data availability and quality, and potential for wider adoption to NHS/statutory health and social care services. (Phase 2, 3);
8. using all qualitative and quantitative study findings, inform the development of a future trial, if the intervention proves feasible (Phase 3).

4. Health technologies being assessed

The health technology being assessed is a peer-delivered, relational intervention for people who are homeless, or at risk of becoming homeless, with problem substance use. The intervention, informed by the concept of psychologically informed environments (6,53), will provide practical and emotional support, for a period of up to 12 months (12 months for the majority of the sample, some will have a short version depending on when they are recruited). Peer Navigators will support participants to stabilise their lives through the development of trusting relationships. The Peer Navigators will help people to engage with services that can meet their health and social needs on their own terms, for example in ensuring that they are registered with GPs, dentists and optician services, if they wish to be, and receive appropriate assessments by such services (12). We are not able to describe the intervention more fully at this stage because it will be co-produced in detail in Phase 1 of the study with a range of collaborators with selected expertise. When the relationship has developed, and participants are willing, a holistic health check based on the UK Guidelines for the Clinical Management of Drug Dependence (64) will be undertaken by researchers (Carver/Foster) to identify specific needs related to mental/physical health, and problem substance use (measures detailed below). These checks will be offered twice, once at the beginning of the intervention and a second time near the end. This is an essential aspect of the proposed intervention and responds to current guidance in the homelessness literature (12,62). We envisage these checks taking place in a private space with the researchers (Carver/Foster) taking sufficient time to work through each of the measures with the participant and allowing time for full discussion. The measures will be paper based and conducted in a sensitive and relational manner. The Peer Navigators will be available throughout if the participant wishes to have their support. Onward referral to specialist services will be supported by the Navigators, as required, and support will be offered for up to 12 months and not withdrawn on the basis of continued problem substance use or abstinence. The comparator will be two standard care sites and the health care check measures will be used by staff in these settings with a sample of residents/service users.

5. Research Plan

The study comprises of three main phases.

Phase 1
Phase 1 (months 1-3) will address Objectives 1 and 2:

1. develop an intervention using co-production for use in community outreach/hostel settings;
2. create a manual to guide the intervention and an associated staff training manual.

The intervention will be co-produced by:

a) experts in homelessness, inclusion and health and psychologically informed environments and relational interventions;
b) representatives from homelessness and third sector organisations;
c) peers and people who are homeless with problem substance use via our PPI group and the Peer Navigators;
d) health/medical professionals from Edinburgh Access Practice.

We will create a bespoke intervention with associated manual and staff training guidance. We will do this by convening a full day meeting (month 2) to discuss the key components of the intervention and how these will be implemented. During this meeting we will plan for the intervention end point in a way that is sensitive to the fact that participants who engage will have experienced many other relationship losses. We will aim to ensure that participants are connected to other support agencies before intervention end. Following this full day meeting, the study team will develop draft versions of the intervention and training guidance for circulation to all parties. A second meeting (month 3) will then be convened to discuss the products with stakeholders including senior managers from the settings we will be using, and refine them. We will work closely with all organisations and individuals, including the Peer Navigators, to ensure that these documents meet the needs of the target group drawing on current literature and stakeholders' own experience of working in the field and/or accessing services as a service user. In line with other relationship-based therapies, manualisation of the intervention will be flexible rather than completely structured, as rigid approaches can reduce effectiveness (65); but will include instruction on psychologically informed environments, health check/measures and referral pathways. In developing the intervention/manual, we will follow the guidelines set out in the literature (66,67). The manual/guidance will be further refined post-intervention and evaluation as one of the study outputs.

Phase 2
This phase will address the following objectives:

3. test the feasibility of recruiting to the intervention, and measure rate of recruitment/attrition in order to determine appropriate sample size and follow up rates for a full RCT;
4. deliver a non-randomised, peer-delivered, relational intervention based on principles of psychologically informed environments, with integral holistic health checks (conducted by researchers Carver/Foster) based on already identified outcome measures;
5. assess the acceptability and feasibility of all procedures in the intervention using Normalisation Process Theory, including staff and participant perceptions of its value, strengths and challenges;
6. assess the acceptability of the holistic health checks, and all identified outcome measures, to determine the best way to measure outcomes for this particular intervention and population in a future randomised trial;
7. assess fidelity, adherence to manual, 'fit' to context, and data availability and quality, and potential for wider adoption to NHS/statutory health and social care services.

Phase 2 (months 4-21) is a non-randomised feasibility study that will deliver the co-produced intervention in six third sector intervention sites. Four part-time (30 hours per week) Peer Navigators will be employed by the Salvation Army for a total of 18 months each to include: three months for the intervention development stage; induction/advanced training in a range of areas relevant to the intervention; recruitment to the intervention for an estimated eight weeks; 12 months for intervention delivery; and four weeks at the end of the intervention for contingencies e.g. final team meetings, debriefing and/or additional time if recruitment runs longer than expected.

Two of the Peer Navigators will work between three homeless outreach services in Lothian, Scotland, and two Peer Navigators will work between three English Salvation Army hostels. The Navigators will be recruited and employed by the Salvation Army. Each Peer Navigator will be located in a place of work but with the expectation that they work across two/three settings where needed to cover holidays/absences and allow a certain degree of co-working (more practical in the Scottish settings due to proximity of sites but also possible in the English settings).

As part of the proposal development work, Jason Wallace (PPI lead and co-investigator) met with a group of people with lived experience of problem substance use who highlighted a number of issues which the study team needed to address with regard to acceptability of the intervention. One was the importance of practical support to attend appointments, such as bus passes and food. Participants in other studies have also highlighted the importance of receiving such practical support (52) and the positive effect it has (4). In order to provide participants with this practical support the Peer Navigators will have access to small amounts of petty cash held in the service settings.

Recruitment to the intervention will be an ongoing process, intensive in the first two months (October and November 2018), until a desired sample size of 60 participants is reached (caseload of approximately 15 per Navigator), or until the fixed date of the end of March 2019 is reached (combining two trial recruitment strategies identified by Thoma et al. (68)). In order to maximise the intervention resource/potential for further reach should attrition occur, a waiting list will be kept by Peer Navigators. As described in the feasibility study conducted by Ferguson and Xie, which tested a social enterprise intervention with street living youths to reduce mental health problems and high risk behaviours, for each participant that drops out, a new participant can be invited to engage in the intervention (69); in our study this 'cut off' point will be confirmed in the intervention development phase but we are planning for that as end of March 2019. As each site has considerably more people accessing the service than the 60 needed across all six sites we do not foresee any challenges associated with recruitment in this timeframe. Assessment of this process of recruitment, and recruitment rate/retention, are included in our research aims and objectives. In light of the finding by Mills et al., that people who were homeless brought friends with them once they trusted the health care service (21), we will create the opportunity for Peer Navigators to accept word of mouth referrals, provided that potential participants attend the service setting to be properly recruited following informed consent procedures, and that there is caseload space.

Once each participant is successfully recruited to the study, following ethical standards regarding informed consent, the intervention will begin. The Navigators will provide practical and emotional support for each participant for a period of up to 12 months. An essential part of the intervention is the holistic health check in the first few months of the intervention, with timing guided by the participant. This health check will be repeated towards the end of the intervention. The health check will be conducted by a researcher (Carver/Foster) in the service in which the Peer Navigator is based. Participants will be asked about their physical and mental health and substance use using several standardized measures. The researchers will conduct the health check using paper-based versions of the measures, which will then be inputted into SPSS. The health checks will be conducted in a sensitive and relational manner, with the Peer Navigators being available as required by participants.

Data collection for the concurrent process evaluation will start and continue through this phase of the study with quantitative and qualitative data collection conducted across the intervention and standard care sites informed by use of Normalisation Process Theory (9). Monitoring of engagement and attrition will take place alongside the attempted follow-up of a criterion sample of participants who 'drop out'. More detailed information on methods and data collection and analysis, and our use of Peer Researchers, is included below.

Phase 3

Phase 3 (months 18-24) will address our research objectives 3, 5, 6, 7 and 8 (listed above) and involve the analysis and write-up of all study findings (more details in substantive sections below). In addition, the intervention manual/training guidance will be refined to ensure that fit for purpose for wider roll-out in a range of settings, and for a future trial. Findings will be disseminated to a range of audiences.

6. Settings

Three homeless outreach services in Lothian, Scotland, and three Salvation Army hostels in England, have been chosen for implementation of this intervention. All hosting services are non-profit, third sector housing organisations. To enable the study to assess differences between intervention and non-intervention care pathways, we have identified two standard care settings that are similar to the intervention sites e.g. third sector/type of funding/types of staff roles and numbers in place/aims of service. The intervention sites are

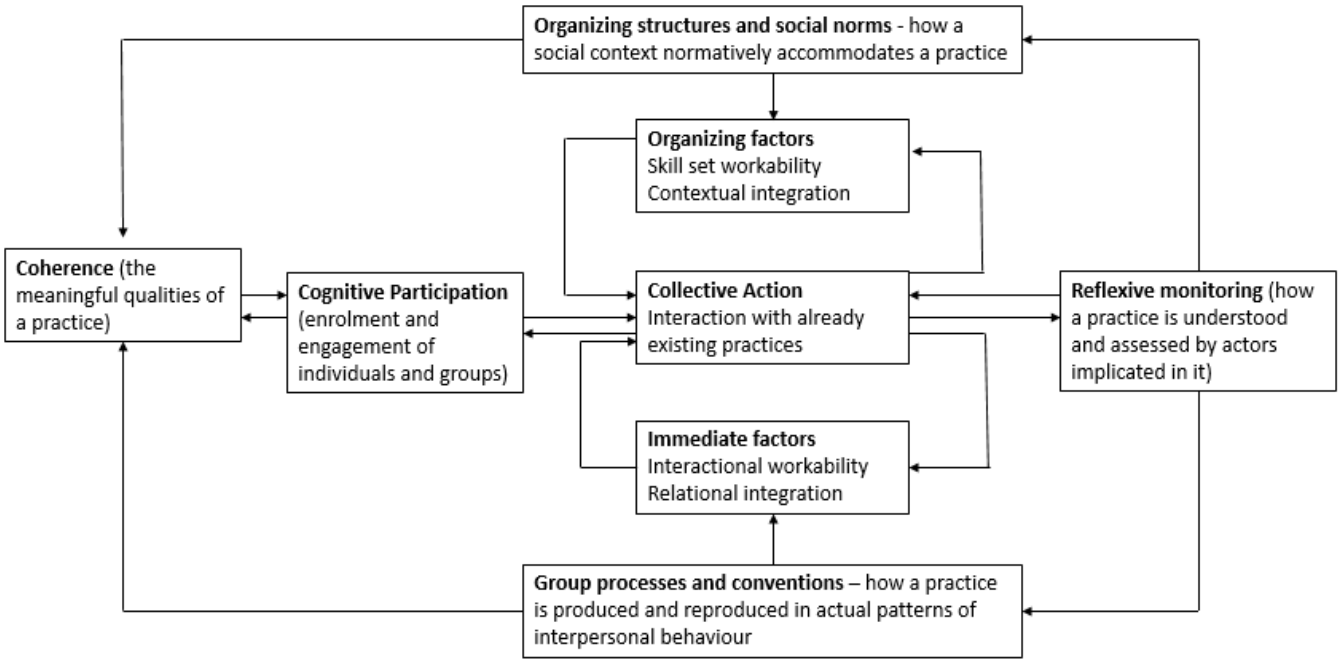
Niddry Street Outreach Service, Edinburgh, run by the Salvation Army; Streetwork's Crisis Service, Edinburgh; and the Cyrenians' Recovery Hub in West Lothian. The English intervention sites are the Orchard Lifehouse in Bradford; and Darbyshire House and Ann Fowler House in Liverpool, both Lifehouses run by the Salvation Army. In Scotland, the standard care site will be the Greenock Floating Support Service in Greenock run by the Salvation Army and Charter Row Lifehouse in Sheffield run by the Salvation Army. In terms of minimising selection bias, we have identified these two as standard care sites, from the wider pool of settings that we have identified. Whether the settings are completely comparable will be explored in the process evaluation. As non-statutory, third sector services, developed to meet the needs of their specific populations, it will be highly unlikely that any service is identical. In the two standard care sites the same health check measures will be used with a sample of residents/service users, as appropriate to these settings, in order to assess population differences and the acceptability of use of measures outside of the context of our specific relational intervention. We will also undertake non-participant observation in both intervention and standard care sites to document similarities/differences between care pathways.

7. Design and theoretical/conceptual framework

The relational intervention will draw on the concept of psychologically informed environments (PIES) (5,53). A recent development in homelessness services, PIEs use a psychological framework to develop services for people with complex histories to enable 'the best chance of sustainably escaping the cycle of poor wellbeing and chronic homelessness' (53, p.4). The traumatic experiences people have had, and ensuing emotional impact, lie at the core of the analysis that PIEs offer (5,6). The coping strategies people develop, including problem substance use, are understood in this context. PIEs aim to enable clients to make changes to behaviours and emotions on their own terms and supportive relationships are key in doing so (6,53). The centrality of relationships within PIEs also lies at the heart of our intervention. Currently there is limited research on PIEs making our use of this 'theory' a novel and potentially unique empirical contribution to the field.

Normalisation Process Theory (NPT) (9) will provide a framework for the evaluation (Figure 1) given it is particularly suited to evaluating complex health interventions by providing a means of improving the way that they are implemented (70).

Figure 1. Model of the components of NPT (71, p.541)



There are four NPT constructs: coherence, cognitive participation, collective action and reflexive monitoring (9). Coherence refers to the process of understanding that individuals/organisations go through to either endorse or prevent and intervention being embedded into practice; cognitive participation involves enrolling and engaging

individuals in the new practice; collective action is the work that individuals/organisations do to embed the new intervention into practice; and reflexive monitoring refers to formal and informal appraisal of the new practice (9,70). In this study, NPT will facilitate analysis of how staff adopt/perceive the intervention, how those receiving it engage, and other contextual factors impacting delivery. Using NPT will enable better understanding of the intervention from the perspectives of all involved and inform a future trial.

8. Target population and inclusion and exclusion criteria

As per the commissioning brief, we aim to engage participants who are 18 years of age or older, homeless or at risk of homelessness, and who have problem substance use. The inclusion criteria for the intervention will be: people who are homeless/at risk of becoming homeless, who self-report alcohol or drug problems. The exclusion criteria for the intervention will be those unable to provide informed consent or aged under 18, those who do not use alcohol or drugs, those who do not self-identify as using substances.

9. Sampling, recruitment and data collection strategy

We are including some information on data collection in this section because of the nature of qualitative research connections between sampling decisions and the methods used. The sample size for the intervention itself will be 60 people, split between the four part-time Peer Navigators in each service setting (n=15 per caseload). The sample size of 60 was determined on the basis that, although sample sizes of between 30-50 have been recommended for feasibility studies (72,73), we expect a degree of attrition/loss to follow-up because of the unstable nature of participants' lives. In consultation with clinical colleagues we have slightly inflated our sample size based on the likelihood of 10-15% attrition to ensure participant volume (68). Importantly, a sample of 60 is also deemed a manageable caseload for the four Peer Navigators (each 30 hours per week).

There are five samples for the process evaluation: participants who complete the 12 month intervention will have quantitative data collected through the health checks; qualitative data will be collected from a purposive sub-sample of approximately one third who consent to take part; participants who drop out who consent to follow up post intervention using criterion sampling; Peer Navigators using criterion sampling; and service staff in the intervention and standard care settings using purposive sampling. The purposive approach will take account of the diversity of settings, gender, age, race/ethnicity, presence of disability or significant health concern, alcohol or drug use as main problem substance for participant samples for the qualitative interviews. Staff samples will be purposive based on diversity of setting, role within service, disciplinary background, gender and age. Foster will recruit the wider service staff (n=16) and participant (n=20-25) samples at each of the six intervention sites. Foster will also conduct all staff interviews using qualitative semi-structured interviews. Peer Researchers will conduct qualitative semi-structured interviews with the sub-sample of intervention participants to examine their views on the intervention at two time points – in the middle and towards the end of the intervention (see Table 1), to explore whether perceptions change over time. They will also attempt to conduct ultra-brief interviews (15-20 mins) with a sample of participants who engage but drop out. Please see Table 1 below for more detailed information.

Table 1. Sampling, recruitment and data collection strategy

Sample	Recruitment strategy and timescale	Data collection methods and proposed sample size
1. Participants receiving the intervention	People who are homeless with problem substance use who are engaged with the intervention A sub-group of those in the intervention will be identified by Foster as the process evaluation sample for qualitative data collection. <u>Timescale:</u> months 10-11 and 16-17	As part of the holistic health check (n=60), standardised measures of socio-demographic characteristics, housing status/quality and general health status; quality of life (SF36); substance use (SURE and MAP); mental health (GAD7 and PHQ9); will be used plus measures to assess relationship quality (CARE). All participants will have this information collected if they consent to the health checks and the data collection component. The health checks will be conducted twice, at the start and end of the intervention by researchers (Carver/Foster). Individual face-to-face interviews (n=20-25) conducted on 2 occasions by Peer Researchers approximately 20-40 minutes in

		duration. Interviews will examine various elements of feasibility and acceptability of intervention
2. Participants who have dropped out	People who are homeless with problem substance use who initially engage but leave the intervention early, identified by Foster and invited to be interviewed once. Timescale: as soon as possible after ending engagement (varies by participant)	Individual face-to-face qualitative interviews (n=10) by Peer Researchers after engagement has ended. Interviews approximately 10-15 minutes in duration. Interviews will examine the acceptability of the intervention and reasons for drop out
3. Peer Navigators	All four Peer Navigators employed for the duration of the project (n=4) in six settings in Scotland and England Timescale: (during training/intervention development, mid-intervention delivery and towards the end of the intervention period)	Individual interviews (n=4) at 3 time points conducted by Foster (approx. 60-90 mins). Interviews examine recruitment, health checks and potential outcome measures, training and support/supervision, fit to context, fidelity, acceptability – topics informed by feasibility study literature (74)
4. Service staff in intervention and standard care settings	Support workers, team leaders, managers/ other staff working in the six intervention sites and two standard care settings. Timescale: months 11-12	Interviews (n=16 across intervention/standard care sites), conducted by Foster (approx. 60 min) and examine issues listed in box above, drawing on feasibility study literature on areas of focus noted above (74)
5. Intervention/ standard care settings	Six intervention sites and two standard care sites will be included Timescale: months 6-11	Semi-structured, non-participant observations in all sites to gain an understanding of the of the culture and context of the settings, staffing levels, client group, activities provided, and fit between intervention and setting in the intervention sites

10. Data collection, management and risk assessments

10.1 Data collection

This section provides more detail on the data collection plan. As described in the plan above, data collection will be undertaken in Phase 2 of the study. Our methods have been creatively combined to form a package appropriate to the settings, the intervention and the target population, and also to meaningfully involve practitioners and peers/community members in the conception and design. as suggested by Bowen et al. (74).

Data collection for the process evaluation will involve both quantitative and qualitative data collection given this is a mixed-methods feasibility study. To explore the feasibility and acceptability of the intervention, we will conduct interviews with a range of participants at different time points, conduct observations in all sites, all guided by Normalisation Process Theory (NPT) (9). It will involve semi-structured interviews with a sub-sample of intervention participants (including those who drop out), all the Peer Navigators and a selection of other staff in the service settings who will have a view of the demand for, and the practicality of, the intervention. They will also likely have a view of the recruitment processes, the potential outcome measures and the adaptations needed to the intervention itself. The process evaluation will also gather quantitative data from the holistic health check outcome measures used by the Peer Navigators in the intervention settings and by regular service staff in the standard care settings. The holistic health checks are part of the Peer Navigator intervention and we will also be assessing their utility as potential outcome measures for a future definitive trial (i.e. quality and completeness of data).

A small group of Peer Researchers will conduct the process evaluation interviews with participants, and attempt to conduct interviews with those who drop out. Peer research has been argued to be ethically imperative, particularly in areas of social exclusion and potential objectification (75). For a study like this, it is both ethically and methodologically the best approach. As Terry and Cardwell note: *'Peer research is based on the assumption that shared experiences bring a unique quality to research; an understanding and empathy that results in a higher quality and more meaningful research process*' (76, p.7). Our team believes that participants in the intervention will be more comfortable speaking with someone who has been through similar life experiences and that this will lead to 'richer', more 'valid' data being gathered in relation to participant experiences of the intervention (77). Participants will see peers with similar life experiences in multiple roles in the study. Mutual aid and peer support can be critical in supporting people's recovery from problem substance use. Accessible role models can help to challenge stigmatising views of people who use drugs and are homeless (60).

In the proposed study the Peer Researchers will be qualified partly on the basis of lived experience of aspects of severe and multiple disadvantage including problem substance use and street homelessness. They will be recruited by Scottish Drugs Forum (SDF) from their wider pool of Peer Researchers and although trained in research methods they will be further trained in our particular study methods and intervention. SDF regularly conducts research using highly skilled Peer Researchers experienced in conducting health-related research. The Peer Researchers will be actively supported by a User Involvement Officer from SDF on site during interviews.

At recruitment to the intervention, participants will be asked if they consent to participate in the associated data collection element of the study: two interviews. Clear straightforward information will be provided on study risks and benefits to inform decision making to take part. Foster will pass on the contact details of those who have agreed to participate to the User Involvement Officer at SDF who will then plan the data collection periods and travel and accommodation needs accordingly. A small group of Peer Researchers will then conduct semi-structured interviews with the identified sample of participants to examine their experiences of being involved in the intervention (and to address the research objectives most broadly) focusing on acceptability to their lives. Semi-structured interview schedules will be used, drawing on Bowen et al.'s (2009) general area of focus for feasibility studies (74), including the willingness of those in the intervention to be randomised in a future definitive trial. In the data collection visits to the intervention sites, they will work in pairs. For the interviews conducted at the three English sites, the Peer Researchers and the User Involvement Officer will stay for two nights to allow time to conduct these. Mid-length (20-40 min), semi-structured interviews will be attempted with the same participants at two time points (during the middle of the intervention for that person and in the last month of the intervention), as per Table 1. An attempt will also be made to conduct brief interviews (10-15 min) interviews with those who end their involvement in the intervention (n=10, men and women, those who left earlier or later, those with alcohol or drug problems). This will require active follow-up and all involved will respect the privacy of those who do not wish further contact. Such contact will, however, be part of the initial intervention/study informed consent process.

Foster will conduct all staff interviews. In-depth interviews with the four Peer Navigators (60-90 min) will be conducted at three time points (training/intervention development, mid-intervention delivery, post intervention, n=12) to explore issues connected to the acceptability of the intervention for delivery with the target group, and feasibility issues connected to the service settings. The need for adaptations to the intervention, levels of change needed to integrate the intervention into the service settings, and fidelity to it, will also be explored. Sixteen interviews (30-60 min) will also be conducted with relevant professionals/service managers in the intervention settings who have experienced the intervention delivery at first hand) and in the standard care settings as well. Semi-structured interview schedules for the Peer Navigators and the service staff and managers will be developed by the research team, with active input from the PPI group, using Normalisation Process Theory (9) as a framework. All interviews will be transcribed in full, anonymised and then uploaded into NVivo, for computer-assisted software support. Non-participant, semi-structured observations (78) (42 hours, split across all intervention and standard care sites) will also be done by Foster to provide process evaluation data on service contexts. Data will be gathered using fieldnotes following a semi-structured proforma (79) and observations will also be carried out in standard care pathway sites to provide additional comparison data.

10.2 Outcome Measures

The outcome measures that we propose using will include standardised measures of socio-demographic characteristics, housing status/quality and general health status (40); quality of life (SF36, 80), substance use (SURE and MAP, 81,82), and mental health (GAD7/PHQ9, 83,84), and a measure to assess relationship quality (e.g. CARE, 85). Please see Table 2 for further detail of the proposal outcome measures and references to these are provided in our reference list. As literacy problems are common within the target population (86), the researchers (Carver/Foster) will go through each of the measures carefully with participants, reading the statements to them. If literacy problems are highlighted as a problem they wish to address, the researchers (Carver/Foster) will pass this information onto Peer Navigators, who can refer participants to appropriate services. The study team will also ask participants if they are willing to consent to long-term follow-up using routinely collected data and appropriate linkage. Outcome data will also be collected on recruitment rate, engagement, attrition, acceptability, time needed to collect/analyse data, and ethics/equipoise of the intervention to inform a future substantive trial.

Table 2. Details of outcome measures

Measure	Key areas	Components
Demographic characteristics, housing and general health status	Demographic information; housing status and quality; general health status	Name, date of birth, gender/gender identity, marital status, children (any under 18?), literacy/education level; Where are you currently living? Quality of housing if housed (hostel/friends/family); health conditions, medications, health status, future service use
PHQ9 and GAD7	Anxiety and depression	GAD7: 7 items: feeling nervous; worrying; trouble relaxing; restlessness; irritable; feeling afraid PHQ9: 9 items: lack of interest; feeling depressed; sleep; energy; appetite; feeling bad about self; concentration; movement; thoughts of hurting self
MAP (slightly amended to fit homeless population)	Drinking and drug use	36 items: substance use (type/frequency/method); overdose; treatment; injecting and sexual behaviour; physical and psychological health; social functioning; relationships; illegal activities Please note, able to be slightly amended to population as not weighted/scored
SURE	Drinking and drug use	26 items e.g. drinking and drug use; self-care; relationships; material resources; outlook on life; importance of previous items
SF36	Quality of life	36 items: physical and emotional health status; effect on daily activities and social activities; pain
CARE	Empathy in context of relationship	10 items: feel at ease; listening; being interested; understanding concerns; care and compassion; positive; explaining things clearly; helping take control; making plan of action

10.3 Data Management

All Peer Researchers and Peer Navigators will be trained in data management by senior researchers from the study team. All data collected during the project by Peer Navigators, such as participant support plans, meeting notes and appointment information (using a participant ID/initials rather than names) will be stored on their password protected Chromebooks. Paper copies of assessments and other documents with personal data will be stored in a locked filing cabinet located within shared offices in all six settings and research data will be stored on the University of Stirling's Research Drive.

11. Data analysis

Raw data and overall scores from each of the outcome measures (detailed in Table 2 above) will be inputted into SPSS, and analysed using descriptive statistics, to gain an understanding of population characteristics in both the intervention and standard care settings as well as to assess process issues in the collection of these data such as missing/incomplete and poor quality data, data entry issues. Analysis using descriptive statistics is appropriate in feasibility studies (87). Matheson, MacLennan and Foster will be involved in the quantitative data analysis.

The Framework Method (88) will be used for the management and analysis of all qualitative data (interviews and observational fieldnotes) because of its ability to support the analysis of the six different settings as cases and because it allows straightforward within case and between case comparisons (88). Framework involves five stages: (1) familiarisation, where the transcripts are read multiple times; (2) identifying a thematic framework, whereby the researchers recognise emerging themes in the dataset; (3) indexing, which involves identifying data that correspond to a theme; (4) charting, in which the specific pieces of data are arranged in tables according to themes; and (5) mapping and interpretation, involving analysis of key characteristics in the tables and providing an interpretation of the dataset (88). Parkes, Fotopoulou and Foster will be involved in the detailed qualitative analysis work. The observational data will be in the form of semi-structured fieldnotes.

All qualitative data will be analysed with the support of the computer software package NVivo. The staff interviews from the settings will be analysed together and will compare intervention/non-intervention differences. The interviews from Peer Navigators will be analysed together with particular issues specifically noted e.g. fidelity to the intervention, challenges with recruitment and drop out, fit between intervention and contexts. We will collect data at different time points with both Peer Navigators and participants and data analysis will specifically interrogate whether, and how, perceptions of the intervention, its challenges and benefits, changed over time. Data analysis will be iterative throughout phases 1 and 2, supported by use of

Normalisation Process Theory (9) to identify contextual influences on the implementation of the intervention across the different settings.

A sub-group of Peer Researchers will be invited to participate in the data analysis and interpretation, supported by Foster and Fotopoulou. They will be provided with an anonymised selection of interview transcripts and asked to provide their interpretations of the themes arising and their significance (stages 1-3). The transcripts will be provided electronically using the University of Stirling's Research Drive and we will develop a proforma for the purpose. We will also involve the Peer Researchers in stage 5 of the analysis, as a form of 'member checking' to enhance validity and trustworthiness of the study findings (89).

We will combine the quantitative data from the socio-demographic information from participants and outcome measures, and the qualitative data from the staff, Peer Navigator and participant interviews and observation fieldnotes, using concurrent triangulation design (90). This design has a single-phase timing and generally involves the concurrent, but separate, collection and analysis of quantitative and qualitative data. Data sets are merged, typically by bringing separate results together in the interpretation or by transforming data to facilitate integrating the two data types during analysis. Analysis will address all the research questions including whether and how a future randomised controlled trial should be conducted to test effectiveness.

The PPI group will have the opportunity to view the analysis outputs from the Peer Researchers using the proformas, and the research team using NVivo, and comment on differences in interpretations and meaning making between the two. This provides a further element of member checking for validity purposes (91) but also will ensure that the PPI group are informed about the main findings emerging from the study prior to receiving – for comment - the draft study report and other dissemination outputs in the final stages of the study.

12. Dissemination and projected outputs

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. We will follow the 26 item CONSORT checklist for reporting feasibility studies in our outputs (92) which will include the following:

- a final study report to NIHR and, if findings and Steering Group recommend it, a proposal for a full trial;
- revised, finalised intervention manual for effectiveness testing in a full trial;
- revised, finalised training manual for the Peer Navigators, to inform a full trial;
- 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;
- ongoing 'blog' posts on the study via the Salvation Army Centre website and social media postings using Twitter;
- a paper on the use of Peer Researchers written with the Peer Researchers as lead authors;
- 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.

We will feed emerging and final outputs into policy and practice via the following mechanisms.

- Parkes is Deputy Convenor of the Drugs Research Network Scotland, with Matheson (Convenor) and Liddell (NGO representative), which provides a unique Scotland-wide opportunity for Involvement in the next stage of this research to test effectiveness.
- NHS Lothian colleagues will ensure that NHS Lothian are fully apprised of the feasibility study findings and their implications to create the potential for support for the next stage of the research i.e. to test effectiveness.
- Wallace will lead the production of lay summaries of the study with input from Peer Researchers and PPI group.
- External supporting organisations such as Pathway have pledged to help us to use their networks for the benefit of the study, for example by using the Faculty for Homelessness and Inclusion Health, a national network of over 1,000 clinicians focused on the care and treatment of homeless and other deeply excluded groups.

13. Project management and Sponsor

The University of Stirling will act as nominated sponsor for the study and actively liaise with all co-investigators throughout. Contractual agreements will be created for all partner organisations detailing levels of involvement, expected tasks and deliverables, and budgets. Project management will begin before the official start date for; ethics approvals; assembling the PPI/Steering Groups; and producing a detailed timetable to track key milestones and success factors. The project management team will be Parkes, Matheson, Carver and Foster This team will review the achievement of allocated tasks through weekly meetings, and discuss with the wider study team if any slippage/non-delivery is encountered.

In terms of study governance, we will establish a Steering Group in line with NIHR guidance with experts from relevant fields, in addition to our PPI group. Two members of the PPI group will also sit on the Study Steering Group to ensure representation of lived experience (Wallace, Scottish Drugs Forum and Burridge, Pathway). Foster is supervised by the Chief Investigator, and the Peer Researchers will be supervised by the User Involvement Officer and other experienced staff in Scottish Drugs Forum (SDF).

14. Approval by appropriate Ethics Committees and main ethical issues for the study

Ethical approval has been granted by the University of Stirling's NHS, Invasive or Clinical Research Ethics Committee (NICR) and the Salvation Army's Research and Development Unit's Ethics Committee. NHS services are not being used and the study team has received a view from the South East Scotland Research Ethics Service (NHS Lothian) that it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (letter supplied to NIHR in March 2018).

The main ethical issues of this study are ensuring use of appropriate lay language, confidentiality, anonymity, data protection, undue persuasion to participate in interviews, the burden of completing two interviews, disclosure of risk, safety of all staff and volunteer Peer Researchers, the observational element of the study, and dealing with the end of the intervention in a sensitive manner. Our PPI group will ensure the use of straightforward lay language in all study documentation to service sites and participants. Foster, Peer Navigators and Peer Researchers will be asked to sign a form which states they will ensure the confidentiality and anonymity of the participants throughout the study. We will comply with the new General Data Protection Regulation (GDPR) guidance (93). Peer Navigators will not be involved in the recruitment of participants to interviews; Foster will approach participants to ask if they would be interested in being involved in the process evaluation. Participants may feel the burden of completing an interview at two time points. While these interviews will be short (20-40 minutes), they do not have to participate in both interviews and can withdraw at any time.

We will comply with HRA Guidance for Informed Consent and GDPR (93). Participants will be asked to state clearly that they accept and understand limitations to confidentiality within the qualitative interviews and/or discussions with Peer Navigators. These limitations refer to disclosures of current or future intent to harm themselves or others. The disclosure from the participant must include clear indication/intent of current (active) or future threats of significant harm towards a specified person or themselves. If such disclosures do occur, this information will be shared with service staff who will conduct a risk assessment as per their duty of care. In the event of this unusual situation occurring, Foster/Peer Researcher/Peer Navigator who has taken the disclosure would call the Chief Investigator to inform her, with an adverse events form completed.

As noted above, non-participant observation will be undertaken in both intervention and standard care settings to gain an understanding of the context of all settings. This will be part of the ethics application and will not be covert. Individual observations will also be strictly limited. Permission to conduct observations will be sought from managers prior to ethics application. Posters will be placed in the sites to inform staff, intervention participants, and other residents/service users that observations will be taking place on particular days/times, and these will explain what information will be captured in these observations. Foster will conduct the observations and will answer any questions regarding the process. No individual consultations will be observed, and the observations will only take place in communal areas of the outreach services and Lifehouses, so informed consent will not be required from individuals (94,95). If a person does not want to be observed, Foster will stop or take a break.

15. Patient and Public Involvement (PPI) in the study

Peer involvement is integral to our study in all key areas. We will have different levels of PPI in the study: co-investigators within the study team; two PPI members on the Study Steering group; a PPI group; the Peer Navigators; and Peer Researchers. Scottish Drugs Forum (SDF) is commissioned by Scottish Government to articulate the opinions/experiences of those directly affected by drug use to policymakers, and those running drugs services. Two co-investigators are members of SDF staff: Dave Liddell is CEO and Jason Wallace is the National Naloxone Training Support Officer. Jason has extensive expertise in collaborative peer-led research projects and has been involved in all aspects of this study's design/development. As part of the proposal he met with a group of people with lived experience of problem substance use who highlighted additional issues to be addressed e.g. the need for continued engagement if a participant becomes abstinent; for continuity of care for duration of project; the importance of practical support to attend appointments (bus passes, food); and appropriate training/supervision for peer workers. Jason Wallace will sit on the Study Steering Group, alongside Stan Burridge as Pathway's Expert by Experience Project Lead, to ensure inclusion of lived experience experts from both countries. Peer Researchers will be involved in data collection and analysis/meaning-making, as described in detail above.

We have identified a PPI group who will meet face-to-face four times and by conference call three times during the study to discuss the intervention and study development, evaluation analysis, implications and outputs. The group will be led by Jason Wallace, Co-Investigator, and have a female Deputy Chair. All members will be reimbursed for their time and receive expenses. We will follow the guidance in the NIHR INVOLVE briefing notes regarding our PPI work (96).

16. Plan of investigation and timetable

The key tasks/milestones over the two-year study duration are listed in a separate Project Management Plan and a flowchart of the study in Appendix 1.

Key success criteria for the study

- University of Stirling and Salvation Army ethics applications submitted and approved;
- Completion of each phase of the study, as set out in the timetable;
- Successful recruitment of the target sample of 60 participants, and adequate retention to ensure sufficient participant 'volume' to the end of the intervention period;
- Collection and analysis of all required data to inform a future definitive randomised controlled trial;
- Production of study report addressing all research questions, meeting study aims and objectives, and refinement of the intervention manual and staff training resource.

Key risk factors for the study and their management

We recognise that there are a number of risks to progress within this project and only some can be fully considered in advance. During Phase 1 we will develop a risk assessment proforma and some examples that we have carefully considered have been provided in Table 3 below.

Table 3. Key potential risks and mitigation

Potential risk	How we intend to mitigate/manage risk
Study processes	
Delay in ethics approval and PVG approvals	Ethical approval gained before project start. 90% of PVG checks completed in 14 days; 4-6 weeks between Navigators being in post & having contact with service users providing time for PVG checks
Study sites involved not cooperating or funded	Support of all participating study sites secured. Streetwork are funded on a short-term basis so if they lose funding we will work with Salvation Army, to identify another setting
Delays in recruiting to the intervention/attrition	Posters will advertise intervention and Navigators will work with staff in settings to accept referrals. Sample size is relatively small. Team has considerable expertise in working with target population. Informed consent process will seek permission for follow-up contact/interview and wait list will be kept

Intervention fidelity	Peer Navigators will be trained in the intervention and relevant skills, and fidelity will be assessed
Data from potential outcome measures is poor	We will work closely with CHaRT to ensure measures used are appropriate and that Carver/Foster are fully trained in their use. Data will be monitored regularly to ensure quality is high/consistent
Peer Navigators	
Difficulties recruiting Peer Navigators	We will work closely with Scottish Drugs Forum (SDF)/Pathway to recruit Peer Navigators. Initial feedback on the Peer Navigator role from SDF volunteers was very positive
Peer Navigator(s) leaves the project early	We will recruit another Peer Navigator. If there is a gap between the current staff leaving and starting, additional hours can be offered to the other worker
Staff illness or absence – Peer Navigators	Short-term absences: additional hours offered to the second Peer Navigator; long-term absences: recruit again. Navigators employed by Salvation Army, an experienced employer
Peer Navigators may experience triggers that cause them to relapse	Support will be put in place to ensure that the Peer Navigators are well-trained/supported and able to identify any such triggers in advance; all at least 2-3 years post problem substance use. They will have supervision, day-to-day support onsite, support from study team and informal peer support
Peer Navigators not subject to Stirling Data Protection	Peer Navigators employed by TSA and Centre for Addiction Services and Research established to support TSA in their partnerships. We will seek advice from TSA's R&D Department to ensure coverage
Research	
Difficulties in recruiting Peer Researchers	SDF regularly conducts research using Peer Researchers and has successfully delivered a range of projects. SDF also has the capacity to support the short-term redeployment of staff/volunteers
Recruitment issues	SDF's Peer Researchers are experienced in recruiting from vulnerable groups
Relapse of substance use for Peer Researchers	SDF employ a Volunteer Coordinator to ensure there is robust support in place for volunteers with lived experience. A Distress Protocol will ensure that negative consequences of interviews are dealt with
Poor quality of data	Peer Researchers will have skills necessary to gather high quality data, data will also be monitored.
Emotional impact of research on Peer Researchers	Following each interview Peer Researchers will have verbal debrief with User Involvement Officer. 30 minute break between each interview. If needed peer researcher can cancel further interviews, which will be covered by another peer researcher, until they feel able to return to interviewing

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Appendix 1: Flowchart