Protocol for a pilot randomised controlled trial to evaluate Hospital Admission support for people who are Underserved, No fixed abode and Early/iRRegular discharge Study: HAUNERRS

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Abstract

Background: People experiencing homelessness (PEH) face disproportionately poorer health than the general population. Despite this, they face barriers to primary care and over-rely on unscheduled secondary care. Limited available data suggests people experiencing homelessness have high rates of self-discharge from hospital (wards or from emergency departments) against medical advice. To our knowledge, there are no tailored interventions to improve health and wider outcomes in this specific population.
This pilot study aims to test recruitment, retention, data collection and intervention fidelity of a third-sector-led complex intervention for people experiencing homelessness who have recently self-discharged from hospital, Emergency Department or refused an ambulance when one has been called. The intervention (HAUNERRS) aims to improve health and address wider social determinants of health.

Methods: Randomised, two-site, open, parallel-group external pilot trial with qualitative investigation. A total of 30-40 PEH aged 18 years and over will be recruited in Edinburgh and Dundee from third-sector Homelessness services and the streets. HAUNERRS intervention is in addition to usual care and includes structured assessment of health and safeguarding, housing, benefits and access to activities through weekly visits lasting up to six months. It will be delivered by a third-sector practitioner. The primary outcome is feasibility of progression to a definitive RCT, assessed against a priori progression criteria relating to recruitment, retention at 6 months, completeness of baseline and follow-up data, and receiving the intervention as planned. A qualitative investigation will aim to gain insight into intervention acceptability and implementability. Secondary outcomes include exploring participant views of the intervention and acceptability of trial procedures and a selection of health and social care related outcomes have also been selected to assess their feasibility as primary outcomes for a future definitive trial. These include access to healthcare, unscheduled secondary care use, frailty, Emergency Department and Hospital return, mortality, Health Related Quality of Life, illicit drug use, nonfatal overdoses, health service registrations, health confidence and social care measures include housing and income. Analysis of quantitative variables

will include descriptive statistics of recruitment and retention rates and thematic analysis will be used for qualitative work.
Discussion: If the primary outcome is achieved, and qualitative investigation suggests acceptability and implementability, this will suggest merit in progression to a subsequent definitive RCT. The study results will be shared via dissemination activities in the community via plain language summaries and through journals and scientific conferences.
Trial registration: To be registered with ISRCTN prior to recruitment
Keywords: Homelessness, Health inequity, Hospital Discharge

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Conflicts of Interest: The first author worked for Simon Community Scotland for 4 years providing frontline outreach support and continued to work there up to commencement of recruitment. As such he has strong professional relationships with the host organisation in Edinburgh but not Dundee.

Table of Contents

Background **6**
Health inequalities and barriers to care among people experiencing homelessness 6
Patient-directed discharge 6
Extent, drivers and consequences of patient-directed discharge among people experiencing homelessness 6
Evidence of discharge interventions for people who experience homelessness 7
Why third-sector outreach may help 7
Primary Research Questions **8**
Secondary research questions **9**
Methods **10**
Patient and Public Involvement 10
Trial Design 10
Sample size 11
Setting 11
Eligibility criteria **12**
Inclusion criteria 12
Exclusion criteria 12
Handling of events during the trial (not eligibility criteria) 13
Qualitative investigation participants 13
Eligibility for the site and for those delivering the intervention 13
Justification of eligibility criteria 13
Participant identification, approach, and informed consent **14**
Participant identification 14
Provision of study information 14
Capacity to consent 15
Documenting consent 15
Recruitment Flyers 15
Baseline Data Collection **15**
Randomisation **15**
Sequence Generation 15
Type of Randomisation 16

Allocation Concealment 16
Randomisation Process 16
Blinding 17
Follow-up 17
Safeguarding 17
Remuneration 17
Withdrawal 18
Post-study support 18
Study Flowchart 19
Intervention 20
Why 20
What (materials) 20
What (procedures) 21
Who 22
How 23
Where 23
When and How much 23
Tailoring 23
Modifications 23
How Well 23
Usual Care 24
Data collection 24
Primary outcome measures 24
Secondary outcomes measures 25
Quantitative data 25
Qualitative component and associated outcomes 25
Analysis 26
Reflexivity 27
Trial Steering Committee 28
Data management 28
Discussion 28
Study limitations 29
Ethics 29
References 29

List of Abbreviations

CHIH	**Centre for Homelessness and Inclusion Health, The University of Edinburgh**
DAMA	**Discharge Against Medical Advice**
FEANTSA	**European Federation of National Organisations working with the Homeless**
HAUNERRS	**Hospital Admission support for people who are Underserved, No fixed abode, and Early/iRRegular discharge Study**
HiSS REC	**Health in Social Sciences Research Ethics Committee**
NICE	**National Institute for Health and Care Excellence**
PEH	**People Experiencing Homelessness**
PDD	**Patient Directed Discharge**
PPI	**Patient and Public Involvement**
PRO	**Patient Reported Outcome**
RCT	**Randomised Controlled Trial**
REC	**Research Ethics Committee**
SCS	**Simon Community Scotland**

Background

Health inequalities and barriers to care among people experiencing homelessness

People experiencing homelessness experience severe health inequities (1), including high levels of multimorbidity (2), premature ageing (3–8) and markedly reduced life expectancy, with estimates in Scotland indicating that women who experience homelessness have a life expectancy between 35-44 years and men 45-54 years (9,10). Many adverse outcomes are potentially preventable with timely and effective care (11,12), yet PEH face substantial barriers to primary and community-based services, including difficulties with registration, access, stigma and necessary trauma-informed support (13,14). Lack of access to primary care undermines preventive and community-based support, leaving PEH to either seek care late through secondary care or to have little sustained contact with health services altogether (15). As a result, unscheduled acute secondary care often becomes a key point of healthcare contact (16), where PEH also face structural and interpersonal disadvantages that impede effective treatment (17–19).

Patient-directed discharge

Among people experiencing homelessness, secondary care is often disrupted by patient-directed discharge (PDD), which is a critical, yet under-addressed, driver of poor outcomes (20). PDD occurs when a person leaves either before clinical assessment or before their discharge has been agreed by professionals responsible for their care, with or without discussion with staff (20). There is a range of terminology used to refer to PDD, including self-discharge, irregular discharge, and discharge against medical advice (DAMA), and (particularly for Emergency Departments) 'left without being seen'.

In this study, patient-directed discharge is used to describe interruption of acute healthcare before assessment, treatment or discharge planning has been completed, including self-discharge from hospital wards or Emergency Departments. We also include refusal of ambulance conveyance after an ambulance has been called. Although clinically distinct, ambulance refusal represents a related form of patient-directed interruption of intended urgent care and may arise from overlapping factors such as mistrust, stigma, trauma, competing priorities and fear of losing accommodation.

Extent, drivers and consequences of patient-directed discharge among people experiencing homelessness

Routine recording of PDD is limited in the UK, but available evidence suggests that PEH experience substantially higher rates than the general population (20,21). UK estimates suggest PDD occurs in approximately 1–2% of general inpatient admissions (22), compared with 11% in a Scottish cohort of PEH (18) and around 16% in pooled English estimates (20). There are also comparable or higher levels of PDD reported in overlapping populations such as people with substance dependency and mental health issues (23–25).

Qualitative studies suggest that PDD among people experiencing homelessness is shaped by interacting clinical, social, and structural factors, including symptoms associated with withdrawal and untreated pain (26); stigma (27,28); mental health problems (29); neurodiversity (30); low literacy (31); and acquired brain injury (32) and competing survival priorities. These drivers are reflected in evidence on the risk of PDD being concentrated among people with experiencing severe and multiple disadvantages (33).

Patient-directed discharge is associated with incomplete treatment and disrupted follow-up, leading to greater risk of unplanned reattendance to hospital, untreated illness and death (34,35). In one

Scottish study, among people who use drugs and self-discharged, 54% of PDD were readmitted to hospital within 30 days (23). It may also worsen housing outcomes, including rough sleeping after hospitalisation (20). The harms associated with PDD often manifest in the community, where fragmented care may impede timeous and comprehensive support and recovery.

Evidence of discharge interventions for people who experience homelessness

Evidence from discharge intervention studies suggests that well-coordinated transitions from emergency or hospital care can improve post-discharge engagement with healthcare services, reduce readmission, and increase rates of treatment completion among people experiencing homelessness (36). Previous work in Edinburgh also suggests that integrated hospital-based multidisciplinary teams in infectious diseases may reduce unplanned discharge and improve outpatient follow-up among people who use drugs (23). However, there is limited evidence on tailored interventions for PEH following patient-directed discharge, particularly interventions delivered in the community after disrupted acute-care contact.

Why third-sector outreach may help

Flexible, holistic and person-centred support, delivered within homelessness service settings or through assertive means to find them where they are, can mitigate some of the barriers to accessing healthcare (3,37,38). Third-sector organisations are well placed to provide flexible, relational support, advocacy, and coordination across health, housing and social care, particularly for people who mistrust statutory services or are poorly served by building-based models of care (39–41).

HAUNERRS was developed as a flexible, third-sector-led complex intervention to identify needs, provide relational support and facilitate re-engagement with health, housing and social care following patient-directed discharge. This study builds on the PHOENIx programme of work which is a health and third-sector co-led model (3,37,38). However, it recognises shortages among clinical professionals in Scotland persist (42) and may limit the extent to which PHOENIx be rolled out at scale and pace. Accordingly, this study examines a related complex intervention delivered solely by third-sector homelessness staff, to explore a model that is less dependent on scarce clinical capacity.

Before undertaking a definitive RCT, key uncertainties remain about whether PEH who have recently experienced patient-directed discharge can be identified, recruited, randomised and retained; whether trial procedures and randomisation are acceptable; whether possible tertiary outcomes can be collected; and whether a third-sector-led intervention can be delivered with fidelity. We therefore aim to conduct a two-site randomised external pilot trial with an embedded qualitative study. The primary objective is to assess feasibility of progression to a definitive RCT against prespecified progression criteria. Secondary objectives are to explore intervention acceptability, acceptability of trial procedures, feasibility of candidate outcome measures to inform future trial design.

This protocol describes the planned trial methods before recruitment. Any important changes to methods after trial commencement, including changes to eligibility criteria, recruitment procedures, consent processes, randomisation, intervention delivery, follow-up procedures, outcome measures, progression criteria or analysis plans, will be documented as protocol amendments with reasons. Substantive amendments will be updated in the trial registry and reported in the pilot trial publication, including the timing of the amendment and whether it affected participants already recruited.

Primary Research Questions

Does the pilot RCT achieve a-priori progression criteria for a subsequent definitive randomised controlled trial?

Progression criteria will be assessed across four feasibility domains: recruitment, retention, data collection, and intervention fidelity:

1. 30-40 participants consented and randomised within 2 months
2. At least 80% of participants retained in the study (receiving follow-up data collection in person) at 6 months after recruitment. This will measured as a proportion of randomised participants alive and with capacity at 6 months who have not withdrawn consent at any point during the study period or been lost to follow-up.
3. At least 70% of data collected from participants. Data completeness will be measured as the proportion of randomised participants providing data at baseline and at 6 month follow-up, with a target of 70% at each time point.
4. At least 70% of participants in the intervention arm receiving the intervention as planned? This will focus on intervention adherence, defined as the extent to which participants in the intervention arm engage with the HAUNERRS support offered. This will be measured by the proportion of participants receiving weekly contact with the HAUNERRS practitioner over the 6 month intervention. Target is to have 70% adherence among participants in the intervention arm to the weekly dose, captured in session logs completed by HAUNERRS practitioner.

Progression criterion will be assessed using a traffic-light (red/amber/green system) across the four feasibility domains:

Domain	Green (go)	Amber (proceed with modification)	Red (do not proceed)
Recruitment (number consented and randomised within 2 months)	≥30	15–29	<15
Retention (proportion with any follow-up data at 6 months)*	≥80%	60–79%	<60%
Data collection proportion of planned outcome measures completed across all randomised participants at baseline and follow-up	≥70%	50–69%	<50%
Intervention fidelity (proportion of intervention-arm participants receiving the intervention as planned, according to pre-specified minimum dose)**	≥70%	50–69%	<50%

* Denominator: all randomised participants excluding deaths during follow-up and those who no longer have capacity to consent, which will be recorded separately. In-person and phone follow-up both count; in-person proportion reported as a secondary metric.

**Minimum dose defined as 24 contacts over 6 months, including ≥1 contact within 7 days of randomisation, assessed via contact logs and fidelity checklist. Reported by site and pooled.

Progression to a definitive RCT will be recommended if all four criteria are green, or if ≤1 criterion is amber and the Trial Steering Committee agrees a clearly specified plan. Progression will not be recommended if any criterion is red, or if ≥2 criteria are amber and qualitative evidence indicates systemic feasibility barriers. The Trial Steering Committees recommendation will also integrate qualitative findings on acceptability and implementability, and will not recommend progression in the presence of unexpected safety signals regardless of quantitative feasibility outcomes.

Secondary research questions

There will be a number of secondary research questions to further explore key uncertainties relating to feasibility of trial procedures and the intervention. These include:

- Are trial procedures (consent, randomisation and follow-up) feasible to participants?
- How acceptable are trial procedures to participants? Acceptability of trial procedures. Participant perceptions of acceptability of trial procedures (recruitment, randomisation, overall trial experience) will be assessed through semi-structured qualitative interviews with a purposive sample of participants, conducted at 1 month and 6 months post-recruitment. The researcher will conduct the interview and participant providing the data. Data will be analysed thematically and findings used to refine trial procedures for a future definitive trial.
- What proportion of potentially eligible individuals are not approached at first contact or not able to consent? And what are the reasons for this?
- To what extent can HAUNERRS be delivered as intended by third-sector staff? What barriers and facilitators affect delivery? Intervention fidelity of staff delivery will be assessed primarily by a researcher reviewing session logs and case records (both completed by HAUNERRS practitioners) for a randomly selected 50% of intervention participants and compare these against a checklist of HAUNERRS core components and minimum dose criteria. This will be conducted iteratively throughout the 6 months to inform intervention refinement and trial progression.
- How do participants experience patient-directed discharge or ambulance refusal?
- What contextual factors and perceived mechanisms may influence intervention engagement and health and social care access?
- What is the feasibility of collecting health-economic data for a future definitive trial?
- Is it feasible and acceptable to collect candidate health, healthcare-use and social-care outcomes at baseline and six months?

Data collection will also involve a number of outcomes to test their feasibility as primary outcomes for a future definitive trial and to inform future sample size calculations. Tertiary outcome data will be summarised descriptively; this study is not designed or powered to test intervention effectiveness. Outcome selection was informed by stakeholder consultation, including six patient and public involvement sessions with people with lived experience of homelessness and third-sector staff. Tertiary outcomes include:

- GP registration — whether the participant is currently registered with a GP, recorded as a binary (yes/no) categorical variable. Self-reported by the participant via questionnaire booklet completed with the researcher at baseline and 6-month follow-up.
- Unscheduled secondary care use — Number of unscheduled secondary care events (e.g., emergency department attendances, unplanned hospital admissions, ambulance call-outs), recorded as a count of events. Self-reported by the participant via questionnaire booklet

completed with the researcher, covering a retrospective 3-month period at baseline and months 0–3 of follow-up.

- Non-fatal overdose — Number of non-fatal overdose events, recorded as a count of events. Self-reported by the participant via questionnaire booklet completed with the researcher, covering a retrospective 3-month period at baseline and months 0–3 of follow-up.
- Alcohol use — participant self-reported harmful alcohol use measured by AUDIT-C scores ranging from 0-12 at baseline and follow-up.
- Non-prescribed substance use over the past 28 days — participant self-reported use of non-prescribed substances (opioids, benzodiazapines, cocaine/crack etc.) in 28 days prior to each assessment, recorded as binary yes/no per category.
- Frailty —Level of frailty, assessed using Section 1 of the Frailty and Holistic Health Needs Assessment (FHCNA), producing a structured frailty rating. Completed jointly by the researcher and participant at baseline and 6-month follow-up.
- Housing status — Current housing situation (e.g., temporary accommodation, rough sleeping), recorded as a categorical variable. Self-reported by the participant via questionnaire booklet completed with the researcher at baseline and 6-month follow-up.
- Health-related quality of life — measured using the EQ-5D-5L. Self-reported by the participant via questionnaire booklet completed with the researcher at baseline and 6-month follow-up.
- Health confidence — Participant confidence in managing their own health, measured using the validated Health Confidence Score (HCS). Self-reported by the participant via questionnaire booklet completed with the researcher at baseline and 6-month follow-up.
- All-cause mortality — Occurrence of death from any cause during the follow-up period, recorded as a binary variable (deceased/not deceased). Ascertained by the researcher through review of third-sector case notes across the full 0–6 month follow-up period.

Methods

Patient and Public Involvement

The design of all participant facing materials were iteratively worked on with feedback from the Lived Experience Consultant. The main researcher met with the Lived Experience Consultant seven times over the four months of the research design phase to work on methods, outcomes, and participant facing material. Other representatives of the wider stakeholder group included people working in frontline homelessness services and managers at Simon Community Scotland. PPI sessions were delivered informally through weekly chats with frontline staff over 4 months during the design of the study. This sustained engagement with frontline staff and people experiencing homelessness helped the researcher sustain a strong relationship with key stakeholders in the homelessness sector and to understand what was important and relevant for people working in practice. This follows MRC Framework which advises the participation at all stages of the study, including development and study design (44). PPI input will continue to inform all aspects of the study.

Trial Design

The study is a two-site, open, two-arm, parallel-group external pilot RCT with an embedded qualitative component. Participants will be randomised 1:1 to HAUNERRS plus usual care or usual care alone. Recruitment will take place over a two month period. Participants allocated to the intervention arm may receive HAUNERRS for up to six months.

A modest qualitative component will be undertaken within the pilot RCT, informed by MRC guidance on process evaluations of complex interventions (44,45). Following this guidance, it aims to identify some of the key uncertainties relevant to progression to a definitive trial.

The qualitative work will also be informed by a 'missingness' lens (46), an include a focus on experiences of self-discharge, barriers and facilitators to healthcare engagement, experiences of support and stigma, the practical work of implementing the intervention, and implications for refining both the intervention and trial procedures.

HAUNERRS will be delivered by practitioners employed by third-sector staff who also provide existing homelessness outreach and support services in Edinburgh and Dundee, which may be accessed as usual by participants in either trial arm.

A two-site pilot design was chosen to allow close monitoring of recruitment, randomisation, intervention delivery, usual-care pathways, data collection and follow-up before considering a larger, multicentre definitive RCT. Edinburgh's relatively developed homelessness health and in-reach services will be considered when interpreting feasibility, intervention contrast and generalisability to other settings.

Sample size

As this is a feasibility study, a formal sample size calculation is not required (47). Although Chief Scientist Office (Scotland) guidance suggests that pilot RCTs may often include 50–60 participants, methodological literature indicates that smaller samples are justified for pilot studies that aim to measure rates of recruitment and retention and refine trial procedures, rather than making claims of effectiveness of interventions (47–50).

In light of the characteristics of the specific population and local prevalence data in Edinburgh and Dundee, the recruitment of 30–40 participants is considered to be both realistic and appropriate for addressing the feasibility objectives of this study. As such, the aim is for approximately 15–20 participants allocated to usual care and 15–20 allocated to usual care plus HAUNERRS.

Setting

The trial will be conducted in Edinburgh and Dundee, Scotland. Both are urban settings with statutory and third-sector homelessness service provision but differ meaningfully in the availability of specialist integrated health and homelessness services.

Edinburgh has the highest number of open homelessness cases in Scotland (51). Usual care for PEH in Edinburgh includes statutory homelessness services, specialist primary care and social care through The Access Place, hospital homelessness in-reach provided, and a range of third-sector outreach and day-centre services. Hospital homelessness in-reach is provided by Cyrenians, a third-sector organisation with four practitioners working across three acute hospital sites and supporting approximately 150–200 unique individuals per month. This service operates independently of trial allocation. At present, post-PDD follow-up is not provided through a standardised pathway; it occurs ad hoc when hospital staff are able to link individuals with an existing third-sector key worker or other community support. The HAUNERRS intervention in Edinburgh will be hosted and delivered by Simon Community Scotland from the Edinburgh Support Hub.

Dundee does not have a specialist, integrated health and social care service for people experiencing homelessness, nor a dedicated hospital homelessness in-reach team. Community health support for PEH in Dundee is available through health navigators and third-sector services. A key third-sector

provider in Dundee is Parish Nursing Dundee, based in the city centre. Parish Nursing operates twice-weekly drop-in sessions and provides one-to-one support for people experiencing or at risk of homelessness, addressing health concerns, harm reduction, recovery support, and social connection. The service is delivered by a team of 3 registered nurses, a recovery support worker, an assistant, and trained volunteers, working in collaboration with the NHS Homeless Health Team and the NHS Mobile Dental Team. Parish Nursing Dundee is the host organisation for HAUNERRS delivery in Dundee. The HAUNERRS intervention will be delivered as a structured addition to Parish Nursing's existing services; Parish Nursing's existing drop-in and community services remain available to all Dundee trial participants irrespective of allocation.

The different service landscapes in Edinburgh and Dundee mean that the usual care comparator differs between sites. Edinburgh has substantially greater existing specialist provision for PEH, including dedicated hospital in-reach. This is a known and accepted feature of the trial context, reflecting real-world variation in service provision across Scotland. The qualitative investigation will include examination of the support received by participants in both arms across both sites, enabling assessment of contamination and contextual variation.

Eligibility criteria

Inclusion criteria

Individuals will be eligible if they meet all of the following at the point of consent:

1. Aged 18 years or over.
2. Currently experiencing homelessness, defined using the ETHOS Light typology as rooflessness, houselessness, or living in insecure or inadequate accommodation at the point of consent.
3. Self-reported patient-directed discharge (PDD) event within the past 8 weeks, defined as any of:
    - left an inpatient hospital ward before being formally discharged or before staff advised it was medically safe, including leaving against medical advice or leaving without informing staff;
    - left the Emergency Department before being seen by a clinician (left without being seen) or after being seen but before assessment/treatment was completed (left before treatment complete);
    - declined conveyance to hospital after an ambulance attended and conveyance was advised or offered, regardless of whether the ambulance was called by the participant or a third party.
4. Has capacity to provide informed consent. Willing and able to provide informed consent and to participate in follow-up over six months.

Exclusion criteria

Individuals will be excluded if any of the following apply at enrolment:

1. Currently residing in a setting providing 24-hour on-site clinical or nursing care (e.g., hospital, care/nursing home, or inpatient detoxification/rehabilitation with on-site clinical staff). Hostels, bed and breakfasts, temporary or supported accommodation, and Rapid Access Accommodation do not constitute exclusions.
2. Lacks capacity to provide informed consent at enrolment.

3. Currently in the custody of HM Prison Service.

Handling of events during the trial (not eligibility criteria)

Readmission during the study is not a reason for withdrawal. Participants who are readmitted remain in their randomised arm, are analysed by intention to treat, and continue to be offered HAUNERRS where allocated.

Entry into custody during the study will be recorded. Participants will remain randomised and included in intention-to-treat analyses; intervention delivery will be paused and follow-up will be attempted on release.

Qualitative investigation participants

Eligibility criteria for each qualitative participant group are as follows:

- Trial participants: purposively sampled from enrolled participants to reflect their housing situation, PDD type, trial arm, and engagement level. Sufficient spoken English to be interviewed without an interpreter.
- Intervention providers: third-sector practitioners who delivered HAUNERRS during the trial and a manager in the service.
- Wider stakeholders: hospital homelessness in-reach staff and ambulance staff involved in supporting participants.

Eligibility for the site and for those delivering the intervention

The trial will be delivered in third-sector daycentres in Edinburgh and Dundee with outreach support to appointments and other intervention components. These sites were selected as they are frequently used by people experiencing homelessness and thus likely support the largest volume of eligible people. The sites also have established third-sector and hospital pathways and the researcher can closely monitor the site. Eligible identification and referral pathways include referrals through the street outreach team, through daycentre staff, and Housing First key workers involved in their care.

Justification of eligibility criteria

This pilot deliberately adopts a broad, inclusive definition of homelessness based on ETHOS Light Typology, rather than a narrow definition. This approach is intended to include people experiencing hidden homelessness (e.g., sofa-surfing, temporary accommodation, precarious arrangements) and reflect the heterogeneity of homelessness in this population.

Eligibility relies substantially on participant self-report (of homelessness, the qualifying PDD event, and service contact). This is a pragmatic choice appropriate to the population and setting, where routine records are incomplete and formal verification may be stigmatising or infeasible. A key pilot objective is therefore to assess the workability, understanding, and potential misclassification of these self-reported eligibility criteria. Baseline housing circumstances (ETHOS Light category), the qualifying PDD type, time since PDD, and recruitment/identification source will be recorded for all participants to allow transparent description of the sample and to inform definitive-trial eligibility criteria.

Participant identification, approach, and informed consent

Participant identification

Potential participants will be identified through third-sector support workers through routine contact with PEH. Individuals who have had a recent hospital admission, emergency department attendance, or ambulance contact that ended in PDD or other incomplete care commonly trigger follow-up health and social care support; eligible participants are therefore likely to be known to third-sector staff through usual service provision.

With the individual's agreement, a third-sector support worker will facilitate an introduction to the research team and help arrange a meeting at a location chosen by the potential participant. Meetings may take place at third-sector venues (e.g., the Edinburgh Support Hub); in the person's accommodation (e.g., Rapid Access Accommodation, supported accommodation, temporary flats); or on the street, provided that privacy can be respected.

To reduce selection bias associated with recruiting only from building-based services, recruitment will include community/outreach routes as well as venue-based routes. However, researchers will not approach individuals in public places (e.g., on the street) without prior coordination with third-sector staff and confirmation that it is appropriate and safe.

The study will apply the Belmont principles in a contextually sensitive way during recruitment by using third-sector staff to facilitate a safe approach (52). This is particularly important for PEH who have self-discharged as they may be acutely unwell, distressed, or intoxicated at the point of contact. Third-sector staff will act as gatekeepers and advise whether it is appropriate to approach an individual at a particular time; however, all recruitment discussions and study procedures will be undertaken by the Principal Investigator (PI) or other University of Edinburgh researchers. Researchers will not approach individuals in public settings without prior coordination with third-sector outreach staff and confirmation that doing so is appropriate and safe. Care will be taken throughout recruitment to protect privacy. If an individual appears to be in crisis, critically unwell, or too intoxicated to engage meaningfully, recruitment will be deferred and usual care and safeguarding procedures followed. The University researcher will record deferrals and the reasons for them will be recorded in an anonymous deferral log with a date and whether re-approach is appropriate. This pre-screening deferral log is only for counting deferred approaches for feasibility purposes, it will not be used to track potential participants. Third-sector staff's service knowledge is what allows for safe re-approach. If the third-sector gatekeeper deems it appropriate, individuals may be re-approached at a later time.

Provision of study information

Eligibility will be confirmed through the individual self-reporting current experiences of homelessness and recent experience of patient-directed discharge within the last 8 weeks. The researcher will then provide the Participant Information Sheet (Supplementary Material). Given evidence of low literacy among PEH (53), researchers will make no assumptions about reading ability and will read the materials out loud. The Participant Information Sheet is designed accessibly and the researcher will go through the information verbally. Explanations will emphasise the voluntary nature of participation; the distinction between research and service provision; randomisation and what each trial arm involves; what support remains available regardless of participation.

Potential participants will be given time to ask questions and will be offered at least 24 hours to consider participation. The researcher will return the next day or at the next available opportunity to

complete written informed consent and baseline procedures. Where the person has reviewed the information, had questions answered, and explicitly expresses wishes to proceed sooner, the 24-hour consideration period may be waived and consent (and baseline/randomisation) completed at the same visit, provided capacity and voluntariness are confirmed.

Capacity to consent

Only individuals who are fully oriented and able to provide informed consent will be enrolled. Capacity will be assessed in accordance with the Adults with Incapacity (Scotland) Act 2000. Researchers will judge capacity through considering the person's ability to understand the relevant information and communicate their decision; they will speak to practitioners who know the person, to gain supporting information that adds context; and use the simply flow chart in the Participant Information Sheet to explain choices and consequences of participation. Individuals who are judged to lack capacity to consent at that time will not be recruited and will be eligible to be re-approached later if capacity is regained (with gatekeeper input).

Documenting consent

Informed consent will be recorded either by written signature on the consent form or where required, audio-recorded. Participants will be given the Participant Information Sheet (Supplementary Material) to keep, along with a debrief sheet (Supplementary Material) summarising what data will be collected, how data will be stored, how to withdraw, and signposted sources of support. Participants will also be asked to provide optional consent for contact regarding being interviewed for the qualitative interviews. They will also be asked to provide optional consent for future linkage of their data (separately from trial participation).

Recruitment Flyers

Flyers will be used in relevant services to enable self-referral. Materials are designed with low literacy in mind and carefully worded and formatted to minimise undue influence (e.g., incentives will not be unduly prominent). An example of the flyer can be found in Supplementary Material.

Baseline Data Collection

After obtaining participant consent, data will be collected via in-person baseline assessments by researchers, which will aim to collect an appropriate range of information for secondary outcomes. An example baseline survey can be found in Supplementary Material. Baseline assessments will take place in person in participants' temporary accommodation, third sector homelessness 'hubs', the street (provided there is adequate privacy) or other low threshold service settings. Baseline interviews will take between 30-45 minutes to complete.

Following baseline, participants will be randomised, and £20 cash will be provided in line with the protocol.

Randomisation

Sequence Generation

Prior to the commencement of recruitment, a single random allocation sequence will be generated by an independent researcher affiliated with the University of Edinburgh, who will have no involvement in participant recruitment, eligibility assessment, intervention delivery, or outcome assessment at any stage of the trial. The allocation sequence will be generated using R statistical

software and will cover the full anticipated sample across both trial sites. The complete randomisation schedule will be produced before the first participant is recruited at either site.

For logistical purposes, the independently prepared envelopes will be divided between the two sites in advance, with each site holding a pre-specified subset of sequentially numbered envelopes. This is a practical implementation arrangement and does not constitute stratification; no attempt is made to balance allocations within or between sites.

Type of Randomisation

Participants will be allocated in a 1:1 ratio to either (a) usual care or (b) usual care plus HAUNERRS, using simple randomisation with no stratification or blocking. Simple randomisation is considered appropriate for this pilot as the primary aim of the pilot is to assess feasibility and acceptability rather than estimate intervention effectiveness.

Allocation Concealment

Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes, prepared in advance by the same independent researcher responsible for generating the allocation sequence. Each envelope will contain a group allocation card indicating the assigned trial arm, corresponding to the computer-generated randomisation sequence. Envelopes will be identical in external appearance, sealed with tamper-evident tape, and signed across the seal by the independent researcher prior to distribution to trial sites.

The prepared envelopes will be divided between the Edinburgh and Dundee sites prior to the commencement of recruitment. Envelopes held at each site will be stored securely in a locked filing cabinet accessible only to the recruiting researcher at that site. The recruiting researcher will open the next envelope in the numerical sequence after confirmation of participant eligibility, completion of written informed consent, and completion of all baseline measures. The following information will be recorded in the site-specific randomisation log at the point of opening: envelope number; participant study ID; date and time of opening; and the name of the person opening the envelope. All opened envelopes will be retained for audit purposes.

Randomisation Process

Participants will be enrolled by the recruiting researcher at each site, following confirmation that all eligibility criteria are satisfied, completion of the informed consent process, and completion of all baseline outcome measures. Randomisation will occur immediately following baseline assessment, prior to any intervention-related activity.

The allocation sequence will have been generated and all envelopes prepared by the independent researcher prior to the commencement of recruitment at either site. Following envelope preparation, the independent researcher will have no further involvement in trial procedures. The recruiting researcher will have no access to the allocation sequence and will open only the next envelope in the numerical sequence at the point of randomisation. The recruiting researcher's lack of access to the allocation sequence, combined with the tamper-evident sealing of envelopes, ensures that allocation concealment is maintained until the moment of assignment.

Participants will be informed of their allocation immediately following the opening of the envelope. For participants allocated to the active arm, the HAUNERRS intervention will commence as soon as practicable following allocation (see Intervention section). HAUNERRS intervention workers will be

notified of a participant's allocation only where that participant has been assigned to the intervention arm, and only after randomisation has occurred.

Blinding

This is an open-label trial. Due to the nature of the intervention, blinding of participants and HAUNERRS intervention workers to group allocation is not feasible. The recruiting researcher at each site will also be unblinded, as they are responsible for informing participants of their allocation following randomisation.

SPIRIT guidance recommends that outcome assessors remain blinded even in open-label trials where possible (54). In this pilot, however, the primary feasibility outcomes are objective, quantifiable metrics and blinding of the outcome assessor would not meaningfully alter their measurement.

Follow-up

In-person data for primary and secondary outcomes will be collected as close to 6 months after baseline assessments as possible. Example follow-up questionnaire can be found in Supplementary Material. Aligned with baseline questions, there will be a combination of study specific questions and structured validated quantitative measures (EQ5D-5L, HCS) which are quick and easy to complete and allow objective assessment of change across the study period.

One researcher will be dedicated to leading follow-up, and will monitor the tracking log and schedules, with weekly reviews of which participants' follow-ups are coming up, who is drifting and who might need outreach. There will a 'target date' with generous windows of one month to follow-up. For the HAUNERRS plus group, to minimise extra travel burden, where possible data collection for follow-up will happen during scheduled HAUNERRS intervention worker visits.

Participants will be asked at baseline 'How would you like us to find you?' and with consent their answers will be recorded on the contact form (Supplementary Material). Participants will be contacted by phone or text as appropriate. If contact is not made then their named 'significant other' will be contacted. If this is unsuccessful then the respective host organisations will be contacted to locate the participant. If contact is made and a face-to-face appointment is not possible then some data collection can be undertaken on the phone.

Safeguarding

The researcher will remain independent of participants' direct care, except in circumstances when there is an urgent need to do so. Such circumstances might include serious mental health crises, including suicidal intent, self-harm or risk of harm to others; or if a participant is showing signs of overdose during the assessments. Any such events will be brought to the Trial Steering Committee.

Remuneration

Participants will receive £20 in cash after each study activity as a token of appreciation for their participation. This includes £20 after the baseline visit, £20 after the follow-up visit, and £20 after any additional qualitative interview they participate in.

Withdrawal

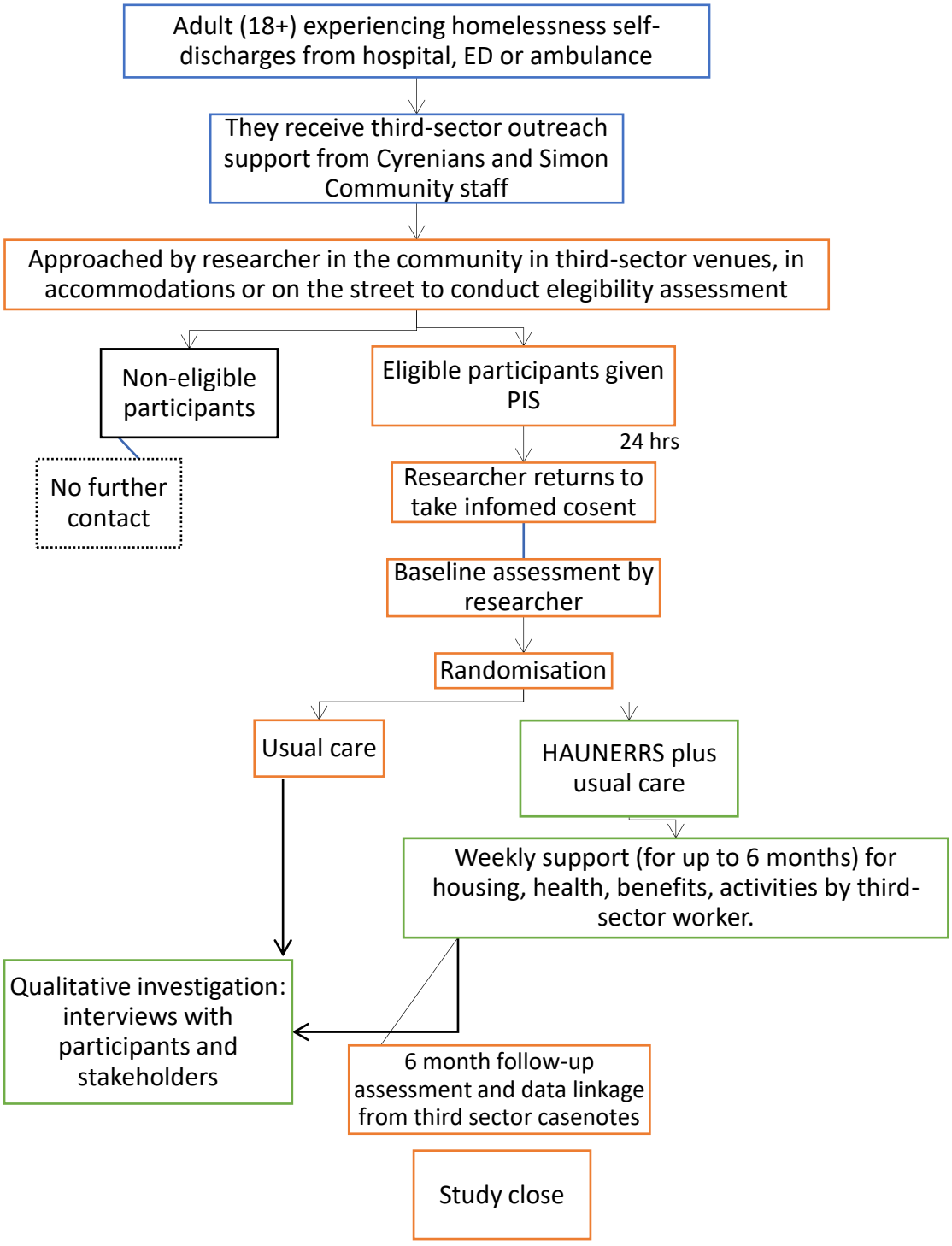
At each contact with the research team, participants will be reminded that they can withdraw from the study at any time, without giving a reason and without any impact on their usual care. Capacity to continue participating in the trial will be kept under review by the researcher for the duration of the participant's involvement. If a participant is assessed as having permanently lost capacity, they will be withdrawn from the trial. Data collected before withdrawal will be retained and included in the analysis, unless the participant requests otherwise where this is possible. If a participant decides to withdraw from the separate, qualitative interview, this will not affect their involvement in the main trial unless otherwise expressed. If an individual does not wish to take part in an interview, or withdraws prior to the interview taking place, no data will be collected from them. If a participant withdraws during an interview, the researcher will stop the interview immediately and ask the participant whether they are willing for any data already recorded to be retained and analysed, or whether they would prefer it to be deleted.

Participants may be withdrawn from the study if they express abusive behaviour such as aggressions, harassment or otherwise unacceptable behaviour to the HAUNERRS intervention worker or research staff. Any participant that dies during their participation will be withdrawn and a serious adverse event report will be recorded. Any participants that meet the exclusion criteria during the study period, such as being accommodated in 24hr medical respite facilities, will be withdrawn.

Post-study support

As the intervention is in additional to usual care, that support will remain in place after the study has ended. There will be a planned tapering phase of a month for HAUNERRS staff to arrange appropriate post-study support for participants. This may include referring them to Housing First or Visiting Housing Support. Part of the qualitive findings will investigate the processes involved with ending the study, with the aim of bring learning to a future trial.

Study Flowchart



Intervention

The HAUNERRS intervention is described below using the TIDieR framework and checklist (55).

Why

Conventional models of healthcare delivery often fail to meet the needs of PEH. PEH are more likely to experience psychiatric and/or physical health conditions requiring inpatient admission (e.g., psychiatric hospitals, general hospitals, rehabilitation centres) (3,16,18,56). Following a patient-directed discharge, discharge planning and coordination with housing, social care, and community health services are disrupted.

Patient-directed discharge (PDD) may also indicate vulnerability and safeguarding risk, reflecting exposure to violence, exploitation and neglect, and in some cases may indicate self-neglect (including disengagement from health and social care where this results in risk of significant harm).

Literature on 'missingness' indicates that people who are absent from routine care (e.g., unregistered with primary care, frequently lost to follow-up, or repeatedly not attending appointments) are more likely to experience PDD and adverse outcomes (15). Aligned with this, HAUNERRS adopts a 'missingness lens' by treating loss of contact as a signal for proactive, flexible outreach and re-engagement rather than passive discharge from services.

Evidence in intervention studies demonstrates that alternative models of healthcare delivery can be effective, including health and third-sector outreach (37) and multidisciplinary Hospital Discharge interventions (57). These interventions are typically multi-component and complex, addressing both health needs and wider determinants of health (58). They are also commonly underpinned by (i) person-centred, strengths-based approaches, (ii) trauma-informed care, (iii) relationship-based engagement as a key mechanism for trust, (iv) harm reduction principles that prioritise safety and reducing risk over 'ideal' behaviour change (59).

The goal of HAUNERRS is to provide flexible, relationship-based support following PDD to: re-establish continuity of care and timely re-engagement with health services; address practical and social barriers to access (e.g., GP registration, transport, phone/digital access, administrative barriers); support housing and wider social support needs as determinants of health; and enhance safeguarding through proactive check-ins and connection to appropriate statutory and third-sector services.

The intervention responds to limited availability of bespoke post-PDD support for PEH in Scotland, despite evidence of need and potential harms.

What (materials)

The resources used to deliver HAUNERRS will include:

There will be a brief non-clinical immediate needs assessment will be conducted organically and iteratively and co-produced support plans.

There will be information on services available. This includes free food places, useful numbers and addresses for more specific support. These documents have already been prepared by Simon Community staff.

We will provide small discretionary funds for a hot drink or basic amenities; bus tickets or taxis to enable attendance at appointments.

Digital inclusion resources will also be provided. This includes a digital needs assessment and access to Simon Community Scotland digital inclusion resources (e.g., phones/tablets/laptops) with support and addition signposting to digital drop-in support.

Finally, harm reduction materials will be supplied. Staff will supply kits of Naloxone and Injecting Equipment.

What (procedures)

HAUNERRS is delivered through a set of core procedures, with content tailored to participant priorities and circumstances.

There will be rapid engagement and immediate needs response (post self-discharge). The HAUNERRS worker will attempt to make contact and arrange an initial meeting as soon as feasible following recruitment. Complete a brief, non-clinical immediate needs assessment to identify urgent concerns (e.g., immediate safety, accommodation status, urgent health needs) and to guide initial support. HAUNERRS assessment tools were designed to provide HAUNERRS intervention workers with a trauma-informed understanding of the person's circumstances and triggers to enable them to support them with health and social care in a tailored way. The tools were developed with PPI input from people with lived experience and staff over four sessions.

At initial contact and throughout the intervention, the support worker will remain alert to safeguarding concerns (abuse, neglect and self-neglect) in line with Adult Support and Protection procedures in Scotland (60). Where concerns are identified, the support worker will take a person-centred approach and seek to agree next steps with the participant wherever possible, consistent with statutory principles (benefit, least restrictive option, participation, and taking account of the adult's wishes and feelings). The support worker will follow Simon Community Scotland safeguarding policies and will escalate to appropriate services (e.g., NHS services, local authority Adult Support and Protection pathways, Police Scotland, or emergency services) when risk is immediate or significant; disclosure without consent will occur only where necessary to prevent serious harm and in accordance with information-sharing guidance. Safeguarding concerns and actions taken will be documented in case records.

HAUNERRS is a non-clinical intervention therefore support workers will not undertake clinical assessment beyond their training and will not provide physical reablement or personal care; where such needs are identified, participants will be supported to access appropriate NHS and/or social care services.

Support planning will be iteratively delivered throughout the intervention. The support worker and participant will co-produce a needs assessments and support plans over time, revisiting and updating goals as circumstances change. Plans will prioritise "what matters to the participant" and may include short-term goals (e.g., replacing lost medication or arranging an urgent appointment) and longer-term goals (e.g., referral to rehabilitation facilities).

Continuity-of-care and support with navigating health, housing and social care is a necessary procedure. Given high levels of missingness in primary care and its association with irregular discharge (15), access to community health services is a core component of this intervention. Participants will be supported to reengage with appropriate services, including facilitating return to hospital when clinically indicated and/or supporting access to community services (GP/primary care, community pharmacy, community nursing, homeless health services, specialist services). HAUNERRS will attempt to address practical barriers to engagement, which may include transport; phone

contact; GP registration; accompaniment and advocacy at appointments; and support to understand discharge documentation.

HAUNERRS will offer housing support**.** Housing-related support will be provided as a core component. This may require complex navigation and advocacy (20). Results will be reported sensitive to context, recognising that outcomes are influenced by structural constraints (e.g., accommodation availability).

There will also be non-clinical medication support**.** HAUNERRS will support participants to obtain and manage prescribed medicines by facilitating access to a community pharmacy; supporting prescription collection/replacement if lost; planning for safe storage; and encouraging adherence via reminders/check-ins. Staff will not administer medicines or store medicines on behalf of participants.

There will be practical and welfare support such as support with banking, welfare and benefits, and personal administration as required. They will also provide referrals for food and clothing bank vouchers and signpost to places that offer hot meals.

There will be harm reduction support. Staff will provide harm reduction services such as Injection Equipment Provision, foil, Naloxone, and Dry Blood Spot Testing). The support worker will also support with accessing other Harm reduction services, such access to Opioid Substitute treatment, Blood Borne Virus medication, and Drug Checking Services.

If participants express interest, staff will signpost to social prescribing initiatives and will help to reduce barriers to access by accompanying people to the activities if necessary. Activities may include peer support, day services, physical activity/leisure access, wellbeing groups, and relevant helplines (e.g., suicide prevention, domestic violence). They will also link participants to Simon Community Scotland weekly activities (e.g., choir, book group, creative writing, art groups, nature walks, peer naloxone training, drop-ins) and signpost to employment opportunities via existing social enterprise schemes.

Digital inclusion support is also a core procedure. Support workers will assess digital access needs and support within their remit. They will signpost to services that provide devices and offer tailored support where appropriate to enable access to online resources (e.g., banking, booking appointments, welfare). They will also signpost to Simon Community Scotland digital drop-in support for additional assistance.

Finally, there will be planned tapering as support is expected to be more intensive/crisis-oriented early after the PDD event and to taper as stability increases, shifting toward community-embedded support and linkage to longer-term services during periods of stability.

Who

The primary providers of HAUNERRS in Edinburgh Simon Community Scotland support workers based at the Edinburgh Support Hub and in Dundee support workers associated with Dundee Parish Nursing. Staff from these organisations are experienced in delivering low-threshold, trauma-informed, person-centred support to PEH via outreach, day-centre, and social prescribing models. These support workers will have Disclosure Scotland checks and have gone through training on psychologically informed environments and trauma-informed care. To provide Injecting Equipment, they will have completed the NHS training and will be licenced to provide Naloxone after doing Naloxone training. BBV Dry Spot blood testing requires additional training.

There will also be additional specialist contributors from Simon Community Scotland digital inclusion team in Edinburgh (delivering digital skills support and/or workshops as needed) and other agencies and clinicians will contribute via referral pathways (not as HAUNERRS intervention providers).

How

Delivery is primarily one-to-one, with a preference for in-person contact. Flexible communication methods are used to maintain engagement including telephone calls and text messaging, depending on participant preference and practical access. Group-based elements are optional and occur only when participants choose to engage in group activities (e.g., social prescribing activities).

Where

In Edinburgh, staff will be based in the Edinburgh Support Hub that is managed by Simon Community Scotland. In Dundee, staff will be based in the Steeple. Both of these venues are in the respective city centres and enables participants to drop-in for support ad hoc and also for HAUNERRS intervention workers to coordinate with other team members. The intervention, however, will mostly be delivered in the community, at locations chosen by the participant (e.g., accommodation settings; community venues such as cafés or museums) to enable flexible, low-barrier engagement and support inclusion in community spaces. It will also be delivered in health settings, through accompaniment and advocacy at health appointments across community services; and if participants are readmitted, staff may provide in-hospital support during admission.

When and How much

The intervention will last for up to 6 months post-recruitment per participant. Participants will be offered weekly planned one-to-one support, with additional unscheduled support provided when required. The intensity of support is flexible and contacts may be higher in the period around the self-discharge event, with tapering over time in line with participant stability and goals.

Tailoring

Tailoring occurs through collaborative goal setting and ongoing support planning. Tailored elements may include:

Understanding and addressing the participants' priorities for health and social care (access to healthcare, housing, benefits, harm reduction, social connection, digital access); the frequency and location of contact will be tailored to the participants' preferences; communication methods will be adaptable (in-person, phone, text); HAUNERRS staff will work hard to understand the participants interests, and select signposting, referrals and social prescribing activities accordingly; finally digital support will be tailored via completion of a digital needs assessment and provision of devices/support aligned to the participant's goals and circumstances.

Modifications

Any modifications to the intervention (content, delivery mode, intensity, or duration) will be documented, including the reason for modification (e.g., participant preference, service constraints, safety considerations, or policy changes). An ethical amendment will be submitted to the Research Ethics Committee for any changes beyond the planned intervention and will be recorded in the protocol amendment form.

How Well

Intervention adherence will be defined as the extent to which participants in the intervention arm engage with the HAUNERRS support offered. This will be measured by the proportion of participants

receiving weekly contact with the HAUNERRS practitioner over the 6 month intervention. The target is to have 70% adherence among participants in the intervention arm to the weekly dose. This will be captured in session logs completed by HAUNERRS practitioner. Adherence data will be extracted from session logs by the research team and reported descriptively by site. Quantitative adherence metrics will be interpreted alongside qualitative data on participant responsiveness captured in follow-up interviews.

Usual Care

Usual care refers to the standard health and social care support that participants would ordinarily receive from third-sector organisations and statutory services in the absence of the HAUNERRS intervention. Usual care differs between the two trial sites, as described below.

In Edinburgh, hospital homelessness in-reach is provided by Cyrenians (61), a third-sector organisation with practitioners working across three acute hospital sites, supporting approximately 150–200 unique individuals per month. During inpatient admission, Cyrenians practitioners work alongside hospital staff to support PEH, building relationships with individuals to help them understand and manage their admission. They provide practical support (e.g., access to a phone or personal items), income maximisation and clinical advocacy, coordination of care between hospital and community services, and discharge planning. In Edinburgh, participants may also be referred to Milestone House, which provides step-down intermediate care to enable continuation of healthcare following hospital discharge.

While Cyrenians Inreach staff deliver some post-discharge outreach in the community, capacity constraints mean this does not occur routinely. When a participant self-discharges, coordinated discharge planning and community liaison are disrupted. In such cases, Cyrenians or hospital staff may refer the individual to third-sector outreach support in the community; however, there is no standardised post-PDD follow-up pathway in Edinburgh.

Dundee does not have a dedicated hospital homelessness in-reach service. Following discharge, community support may be facilitated by the care navigator, who supports individuals to re-engage with community-based services. Community health support for PEH in Dundee is also available through Parish Nursing Dundee, based in the city centre. Parish Nursing operates twice-weekly drop-in sessions providing health support, harm reduction advice, recovery support, and social connection, as well as one-to-one support outside drop-in hours and support groups for people in recovery. These existing Parish Nursing services are available to all Dundee participants irrespective of trial allocation and are therefore considered part of usual care in Dundee. There is no standardised post-PDD follow-up pathway in Dundee; as in Edinburgh, post-PDD support is currently ad hoc and dependent on the availability of existing third-sector contacts.

Data collection

Primary outcome measures

The feasibility of recruitment and randomisation will be measured by the number of individuals invited to participate and the number subsequently recruited at baseline. Participant retention will be assessed by the proportion of participants remaining in the trial at 6 months. Adherence to the intervention will be evaluated according to the proportion of participants engaging with the weekly HAUNERRS support on offer. Completeness of patient-reported outcome data will be assessed by

the proportion of participants who complete outcome assessments at baseline and at follow-up visits.

Secondary outcomes measures

Secondary outcome measures will be a combination of patient-reported and third-sector case notes. There will be a combination of study specific questions and structured validated quantitative measures (EQ5D-5L, HCS) which are quick and easy to complete and allow objective assessment of change across the study period. Intervention implementability and acceptability will be measured by qualitative interviews with a purposive sample of participants.

Quantitative data

Tertiary secondary outcomes will be summarised descriptively by randomised arm using appropriate statistics for each variable type: proportions (with 95% confidence intervals) for binary and categorical outcomes; means and standard deviations, or medians and interquartile ranges where data are skewed, for continuous outcomes. Summaries will be presented according to randomised allocation regardless of adherence or protocol deviation, to mirror the intention-to-treat approach that would be used in a definitive trial and to describe outcomes as they occurred under each allocated condition.

This pilot is not powered to detect or test differences in participant outcomes between arms, and no formal hypothesis testing will be conducted. Preliminary between-arm estimates will be presented for tertiary outcomes where appropriate. These estimates are intended solely to assess the feasibility and variability of outcome measurement and to inform the sample size calculation for a future definitive trial; they will not be interpreted as evidence of effectiveness or lack of effectiveness of the HAUNERRS intervention.

Qualitative component and associated outcomes

We will conduct a qualitative component to answer the following research questions:

The primary research question will seek to answer how feasible and acceptable are the intervention and pilot trial procedures to participants experiencing homelessness and to staff/stakeholders?

Secondary research questions include:

- What factors shape participants' experiences of self-discharge, non-attendance, and disengagement from healthcare and support services?
- How is the intervention delivered and experienced in practice, and what factors facilitate or hinder engagement, sustained contact, and perceived benefit over time?
- How do wider service, organisational, and structural contexts influence intervention delivery, healthcare engagement, and patterns of 'missingness' from services and research follow-up?
- What refinements to the intervention and trial procedures are needed before progression to a definitive trial?

Semi-structured interviews will be conducted with a purposive sample of study participants at two timepoints: firstly, early in the trial (baseline or within the first month) to explore initial feasibility and acceptability of the intervention and trial procedures. And secondly, near the end to explore experiences over time, sustained engagement or disengagement, perceived impacts of the

intervention, and acceptability of trial participation. We will aim to conduct 5-10 participant interviews across the two timepoints. Repeat interviews will be sought with a subset of participants where feasible. Participants will be sampled across both trial arms to capture a range of experiences, including variation in intervention engagement, gender, housing situation, and access to services such as day centres or temporary accommodation. Participants will be asked for consent to contact about being interviewed during baseline. The same consent processes outlined above will be enacted for the participant interviews. If a participant decides to withdraw from this separate, qualitative interview, this will not affect their involvement in the main trial unless they express otherwise.

A small number of semi-structured interviews (n=3 to 5) will also be conducted with staff involved in delivering the intervention and relevant stakeholders to explore how the service was enacted in practice and how wider service and structural contexts shaped delivery and engagement.

Depending on the participant's preferences, interviews will be conducted either in person, over the phone or online. In person interviews will be conducted at a location of the participant's choosing (either in third-sector venues, at accommodation settings or in private areas of cafés). The researcher will contact interviewees the day before the interview, to remind them of the time. Interviews will adhere to the lone-working policy (62). Interviews will last between 30-45 minutes and participants will be paid £20 in cash at the end of the interview to thank them for participation.

The interview will start with an easy and open question which will be followed by asking key questions from the topic guide (see in Supplementary Material). Interviews will be conducted flexibly and in a trauma-informed manner which will be responsive to participant circumstances including fatigue, distress, and time available. Not all questions will be asked in every interview, and prompts will be used selectively. Participants may find some of the topics distressing. If the participant becomes distressed the researcher will terminate the interview and offer support by signposting to appropriate services

Interviews will be audio-recorded with consent, transcribed verbatim, anonymised, and stored securely on DataStore in accordance with the University of Edinburgh's data management procedures. They will be audio-recorded on an encrypted device. If a participant does not consent to audio-recording, they will be asked whether they consent to handwritten notes being taken instead. If they consent, the interview will proceed and the handwritten notes will be anonymised, stored securely, and treated as qualitative research data; if they do not consent to either audio-recording or handwritten notes, the interview will not proceed and no interview data will be collected. The services of Edinburgh University's transcription service may be used to transcribe interviews. If so, Edinburgh's Electronic Transcription and Translation of Audio service, ETTA, complies with GDPR regulations and policies for the secure and sensitive handling of sensitive information.

Qualitative findings will be used to interpret pilot trial outcomes, including intervention engagement and trial retention, and to inform refinement of the intervention and trial procedures before a definitive study. Thematic analysis will be used to analyse the qualitative data.

Analysis

Analyses will focus primarily on feasibility outcomes, including recruitment rate, consent and randomisation procedures, intervention delivery, participant retention, and completeness of outcome data. Feasibility outcomes will be summarised using descriptive statistics, including frequencies, proportions, and where appropriate means and standard deviations or medians and

interquartile ranges. Feasibility outcomes will be assessed against the pre-specified traffic-light progression criteria described in the Primary Research Questions section. The overall progression recommendation will be made by the Trial Steering Committee, integrating quantitative feasibility findings with qualitative evidence on acceptability and implementability from the embedded process evaluation.

Tertiary outcomes will be summarised descriptively within each randomised arm using statistics appropriate to each variable type: proportions for binary and categorical outcomes; means and standard deviations, or medians and interquartile ranges where data are skewed, for continuous outcomes. Where appropriate, estimates of between-arm differences will be presented with 95% confidence intervals to indicate a possible direction of effect; these estimates are exploratory in nature and should not be interpreted as evidence of effectiveness.

The extent, pattern, and documented reasons for missing data will be summarised descriptively by outcome, timepoint, and trial arm, as completeness of outcome data is itself a key feasibility outcome. These findings will inform strategies to minimise missing data and the approach to handling it in a future definitive trial.

Qualitative interview data will be analysed using reflexive thematic analysis (63), with the aid of NVivo qualitative data analysis software. Analysis will be ongoing and iterative throughout data collection rather than conducted solely at the end of the study, allowing emerging themes to inform subsequent interviews. Qualitative findings will be used to interpret pilot feasibility outcomes, including patterns of intervention engagement and trial retention, to assess acceptability of trial procedures and the intervention to participants and staff, and to identify refinements needed before a definitive trial. Qualitative findings will also directly inform the Trial Steering Committee's overall progression recommendation alongside the quantitative feasibility outcomes.

A statistical analysis plan (SAP) will be finalised and dated prior to the completion of recruitment and before any outcome analysis. Given the descriptive, feasibility focus of this pilot, the SAP will pre-specify the definitions and denominators of all feasibility outcomes, the progression criteria and decision rules, the descriptive summaries for candidate outcomes, and the handling of missing data; no inferential hypothesis testing is planned. The SAP will be made available on request.

Reflexivity

The qualitative component of this research demands reflexivity: this research will form the basis of my (CN) PhD research. I'm working together with my supervisors, who will provide guidance and oversight. I used to work for Simon Community Scotland full time for 4 years prior to beginning the research and continue to work there one day a week (although I will be stopping during the course of the trial). I am therefore likely to know the staff involved in delivering the intervention and many of the participants. I am motivated to conduct this research as I have witnessed many of the health outcomes associated with self-discharge as they occur in practice and am motivated to honour the people I have supported through this piece of work. I have developed caring and supportive relationships with people experiencing homelessness, which has given rise to a sharp sense of injustice at the long-standing disadvantages they face. So I'm carrying a significant bias into this study: the feeling that health and social care providers are not doing enough and have failed to address the needs of this underserved population.

Trial Steering Committee

The Trial Steering Committee (TSC) will be made up from the supervisory team. They will meet every month and be responsive to the needs of the trial. The TSC will give guidance on practicalities of the trial, as well as ensuring the ongoing safety of study participants. As this is a small, short pilot, and primarily focussed on feasibility, there is no planned, independent Data Monitoring Committee (DMC). Instead, the TSC will take on the role of the DMC. This role will be responsible for the overall conduct of the trial, for safeguarding the interests of the trial participants and for assessing the safety of the intervention.

Data management

All study data will be handled confidentially in accordance with relevant research governance arrangements, the UK GDPR and the Data Protection Act 2018, and University of Edinburgh information security policies. Data will be collected by the researcher. Participants will be assigned a unique study ID; identifiable contact details will be stored separately from research data.

Electronic data (including any personal or health information) will be primarily stored in secure, restricted access folders in DataStore. This will be automatically backed up. They have use University security controls (e.g., multi-factor authentication and encryption in transit and at rest). Access will be limited to the PI and authorised study staff. Only University of Edinburgh devices will be used for data handling and storage.

Interview recordings will be transcribed verbatim, de-identified, and analysed in NVivo; RStudio will be used for quantitative data. Anonoymous reasons for deferral from the 'Deferral Log' will be entered into Excel and stored in DataStore. De-identified transcripts and datasets will be stored in a restricted-access DataStore group space with routine backup and disaster recovery. On study completion, anonymised data will be archived in the University's DataVault (encrypted, access-controlled) for a minimum of 3 years (or as specified in participant materials). Data retention arrangements are described in the participant information sheet and consent form.

Any paper records will be ID-coded (no direct identifiers and no special category data), transported directly after collection, and stored in a locked filing cabinet in University premises with access restricted to authorised study staff. Findings will be reported in aggregate and will not identify individual participants. Confidential, unpublished study information will not be disclosed beyond the study team except where required for governance/monitoring or with prior written Sponsor approval. Any future use of study outputs will be limited to anonymised, non-identifiable summary information for health and care research dissemination and to inform a subsequent application for a definitive trial or service development.

Discussion

As far as we are aware, no published or unpublished RCTs have tested the application of third-sector-led support for people experiencing homelessness who have recently self-discharged from hospital. This study aims to address this gap.

The proposed study is closely aligned with national and international policy commitments to reducing health inequalities, particularly those emphasising the need for innovative, integrated models of care for people experiencing homelessness. The HAUNERRS intervention reflects these priorities by supporting more equitable access to healthcare and improving coordination across

health, housing, and social care services. In the Scottish context, the intervention is consistent with recent policy developments in housing, health, and social care, including new statutory duties under the Housing Act (2025) to strengthen case coordination for individuals with multiple and complex needs (64), as well as NHS Scotland's commitments to community-based support (65) and addressing 'missingness' in healthcare (66).

We plan to share the study results through dissemination activities in the community and relevant stakeholders with the aim of future involvement in a definitive trial. This will be done through presenting and sharing our findings directly with people experiencing homelessness and stakeholders in daycentres, accommodation sites, and other low-threshold venues in Edinburgh. Our research team represent local and national stakeholders in a range of topics associated with this research, including homelessness and substance use. It is anticipated that the researcher Christian Newman will contribute to the writing and editing of manuscripts for publications resulting from the trial and fulfil the International Committee of Medical Journal Editors criteria for authorship.

Study limitations

Given the pilot nature of this study, the study will not be powered to meaningfully evaluate the differences in clinical or social outcome measures. As we are also heavily relying on patient-reported outcomes, this risks having biased estimates and may incompletely capture healthcare utilisation.

The study will also rely on third-sector information on patient-directed discharge which can lead to selection bias as we are likely to only recruit people who already engage with, or at the very least are known to services.

The study will be conducted in one city in the UK and patterns of homelessness and heath needs vary across settings. Social circumstances rely on governance in local city authorities. As detailed in the Usual Care section, Edinburgh has a dedicated hospital homelessness inreach team that consists of 4 practitioners. No other city in Scotland has the same level of resources dedicated to homelessness hospital inreach.

Ethics

This research will comply with the University of Edinburgh's 'Research Ethics Policy' (67) and also the UK Policy Framework for Health and Social Care Research (68). Sponsorship has been obtained from the College of Arts, Humanities and Social Science at the University of Edinburgh (email: Cahss.res.ethics@ed.ac.uk) and a favourable ethical opinion has been obtained from the Research Ethics Committee in the School of Health in Social Science.

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