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Pharmacist and Homeless Outreach Engagement and Non-medical Independent prescribing Rx (PHOENIx): a study protocol for a pilot randomised controlled trial

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ABSTRACT

Introduction The number of people experiencing homelessness (PEH) is increasing worldwide. Systematic reviews show high levels of multimorbidity and mortality. Integrated health and social care outreach interventions may improve outcomes. No previous studies have targeted PEH with recent drug overdose despite high levels of drug-related deaths and few data describe their health/social care problems. Feasibility work suggests a collaborative health and social care intervention (*P*harmacist and *H*omeless *O*utreach *E*ngagement and *N*on-medical *I*ndependent prescribing R*x*, PHOENIx) is potentially beneficial. We describe the methods of a pilot randomised controlled trial (RCT) with parallel process and economic evaluation of PEH with recent overdose.

Methods and analysis Detailed health and social care information will be collected before randomisation to care-as-usual plus visits from a pharmacist and a homeless outreach worker (PHOENIx) for 6–9 months or to care-as-usual. The outcomes are the rates of presentations to emergency department for overdose or other causes and whether to progress to a definitive RCT: recruitment of ≥100 participants within 4 months, ≥60% of patients remaining in the study at 6 and 9 months, ≥60% of patients receiving the intervention, and ≥80% of patients with data collected. The secondary outcomes include health-related quality of life, hospitalisations, treatment uptake and patient-reported measures. Semistructured interviews will explore the future implementation of PHOENIx, the reasons for overdose and protective factors. We will assess the feasibility of conducting a cost-effectiveness analysis.

Ethics and dissemination The study was approved by South East Scotland National Health Service Research Ethics Committee 01. Results will be made available to PEH, the study funders and other researchers.

Trial registration number ISRCTN10585019.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The strengths of this study include the recruitment of patients normally excluded from trials and the collection of diverse health and social care data.
⇒ An individualised, complex intervention of 6–9 months offers longer consultations and integrated health and social care support.
⇒ Mixed methods enable determination of whether a subsequent trial is merited from an efficacy, economic and patient perspective.
⇒ A pilot trial lacks the power to detect a clinically significant effect and recruitment was limited to 20 locations in Glasgow.

INTRODUCTION

Homelessness is a global problem, and the number of people experiencing homelessness (PEH) is increasing worldwide.[1] The individual, societal, health and economic burden of homelessness is widely known and undisputed.[2] The health of PEH is characterised by problems with mental health, physical health, and drug and alcohol use, and they tend to die prematurely at age 41–51 years, with the number of long-term conditions on par with housed individuals almost twice their age.[3–6] A majority of PEH experience problems with polydrug use and the associated high rates of deaths from overdose.[7 8] Other causes of death are also increasing.[5] Homelessness is an independent risk factor for hospital admission and emergency department (ED) attendance, and the rates of ED use are increasing across healthcare systems worldwide.[2] PEH are known to present to the ED late and with comparatively more serious

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Table 1 Trial inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
► Homeless (living in temporary homeless accommodations, no fixed abode or rough sleeping). *And* ► Aged 18 years and over. *And* ► One or more non-prescribed drug overdose in the past 6 months confirmed by self-report and witnessed overdose/ambulance callout/emergency department visit/naloxone use.	► Living in residential or community-based rehabilitation facility which has direct access to in-house medical and nursing care. *Or* ► Unable to give written informed consent.

problems.[2 9] PEH can be overwhelmed by their multiple health and social care problems and lack of support, experiencing individual, structural and institutional difficulties with self-care.[10–13]

The development and testing of complex, integrated health and social care interventions have been highlighted as an important priority, with an associated need to test the impact of longer contact times.[2 4 5 14–16]

Complex interventions for multiple problems

Assertive outreach delivered by workers who can establish trust and develop positive interpersonal relationships is an evidenced approach to strengthening primary health and social care for PEH.[14–17] Partnerships should be built between outreach health services and homeless service providers, who are best placed to support wider needs, including housing, education and employment.[14] PEH perspectives on the effective components of interventions include involvement of peer workers in outreach programmes, help with housing, welfare payments and social prescribing.[9 14 18 19] Interventions limited to addressing single health problems, for example drug use problems or mental health problems, may hold little appeal to PEH who have multiple problems.[2 15]

Interventions in published studies offer housing improvements to PEH with mental health or substance misuse, or target and address single physical health conditions, for example HIV or tuberculosis, without addressing multimorbidity[16 19–23] or diseases thought to be amenable to early intervention, for example cardiovascular or respiratory disease.[5] Of the few robust studies of interventions led by healthcare professionals aiming to improve broad outcomes, for example mortality or reduced ED utilisation, none has been found effective.[23] Interventions to address the multiple needs of PEH are necessarily complex, with a new framework supporting rigorous, phased testing.[24] We are not aware of studies that have followed the recommended development stages for testing of complex interventions, including pilot testing to inform power and sample size calculation for a subsequent definitive trial.[19 24 25] There are also no UK-based intervention studies targeting community-based PEH.[23]

Role of pharmacists collaborating with third-sector homeless workers

Generalists may be best equipped to address the diverse levels of multimorbidity experienced by PEH,[4 15 16] suggesting that testing of holistic medical plus social care outreach interventions for community-dwelling PEH is overdue. However, as workforce shortages worsened by COVID-19 may limit the expansion of the roles of established primary care clinicians, pharmacists with generalist independent clinical prescribing qualifications may have a role. Generalist pharmacist independent prescribers exist across the world, offering a potential solution to ongoing general practitioner (GP) and nurse workforce shortages.[26] Over 7500 (13%) UK-based pharmacists have undergone additional subsequent training in therapeutics and have completed a period of additional supervised clinical training to gain an independent prescribing qualification. This independent prescribing qualification enables diagnosis and prescribing for any condition within the pharmacist's competency. In the UK, pharmacists practise as part of a multidisciplinary health team throughout primary care (in community pharmacies as independent contractors or based in general practice offices as clinical pharmacists) and secondary care. A collaboration between pharmacists and third-sector homeless workers is likely to be welcomed by PEH.[10] Emerging evidence of undertreatment with medicines[3 6] and challenges to medicine adherence,[27] which may be amenable to a pharmacist's intervention,[28 29] both of which may contribute to poor health and premature death in PEH,[2 5] suggests a need to robustly test pharmacist-led, integrated health and social care intervention for PEH.

PHOENIx

Staff working for homeless charities in Glasgow, Scotland (Simon Community Scotland and The Marie Trust) have lived experiences of homelessness and formed a novel, integrated National Health Service (NHS)–homeless sector partnership called PHOENIx: *P*harmacist and *H*omeless *O*utreach *E*ngagement and *N*on-medical *I*ndependent prescribing R*x*.[30–32] The PHOENIx team assertively outreach to various locations in Glasgow, for example homeless congregate accommodations, to engage and offer holistic assessment, treatment, prescribing and referral for patients' expressed health and social care priorities.[30–32] PHOENIx is a secondary prevention intervention aiming to improve self-care and strengthen primary care to reduce the use of ED. The pharmacist is from the NHS and the third-sector outreach worker is from either of Glasgow's homeless charities (Simon Community Scotland or The Marie Trust). Visiting patients once weekly and with consultations lasting an hour on average, previous qualitative work suggests benefit to patients.[33] A feasibility study describes

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the pharmacist assessing, treating and prescribing for acute and chronic health problems, while the homeless charityworker addresses benefits, housing and social prescribing.[32] Working within the clinical governance framework provided by the patient's GP and the local ED, PHOENIx may improve health and reduce emergency health service contacts.[32 33] PHOENIx aims to support PEH in managing their diseases, medicines and treatments. These include helping overcome the workload and the impact of self-management for multiple untreated conditions, which can be overwhelming and can lead to self-medication with street drugs and to overdose. PHOENIx, by building trusting therapeutic relationships, increases access to health and social care, including medicines for multiple conditions. Social support and opportunities for supported accommodation may also help PEH cope with their multiple problems and reduce the risk of overdose. The normalisation process theory (NPT) focuses on the workability of complex interventions like PHOENIx. The NPT is our preferred theoretical framework to aid understanding of how PHOENIx works in the real-world environment of this pragmatic randomised controlled trial (RCT) (a logic model is provided in online supplemental material).

PHOENIx after overdose pilot RCT

Here, we describe the methods of an ongoing pragmatic pilot randomised controlled multicentre trial with embedded economic and qualitative evaluations of the PHOENIx intervention which targets PEH with recent non-fatal drug overdose. The aim of the trial is to determine whether progression to a subsequent definitive RCT is justified based on the rate of participant recruitment and retention at 6-month and 9-month follow-up, fidelity of intervention delivery, and sufficient data collection at baseline and at 6-month and 9-month follow-up, with other outcomes including patient-reported measures and healthcare utilisation. Given the paucity of data informing research and service delivery, we will also collect a diverse range of patient-level health and social care data.

METHODS

Study setting

NHS Greater Glasgow and Clyde (GG&C) provides free primary, secondary and tertiary care to approximately 1.2 million people (almost 25% of the Scottish population). The study is set in 20 Glasgow venues (homeless accommodations or drop-in centres).

Eligibility criteria

Participants

Homeless individuals[14] aged 18 years and over are considered eligible if they have at least one drug overdose in the previous 6 months (table 1).

Interventions

Usual care

In Scotland, PEH are offered a temporary single room in a designated city centre venue, for example hotel, hostel or a bed and breakfast accommodation, and are allocated a named case worker.

Patients with alcohol or substance use problems may receive care and treatment from Glasgow's Alcohol and Drug Recovery Service (ADRS), the Homeless Addiction Team (HAT) or the Heroin-Assisted Treatment Service. Patients can present to any ADRS to seek help and receive same-day assessment. In some circumstances following management of any immediate care needs, they may be supported to engage with another ADRS closer to their temporary accommodation or to which they remain open from a previous treatment episode. If transport to a different base is required at the time of presentation, the service will offer a taxi to facilitate this journey. For people already open to drug and alcohol services, their care and treatment are provided through a combination of phone and face-to-face contact either at the base or on outreach, depending on individual needs and circumstances.

To access primary healthcare, including a GP or an ADRS, PEH must either travel to their registered mainstream or specialist homelessness general practice or contact by phone, which requires them to have access to a mobile phone (which can be supplied by the ADRS or the HAT) or use a landline within their accommodations, if appropriate. All mainstream services operated triage during the COVID-19 lockdown, with requests for patients to phone the relevant care team, if possible, prior to presenting to the premises.

The Homeless Health Service GP practice offered phone in-reach to a variety of homeless accommodation services and restarted outreach after a period of interruption.

For patients with mental health problems without drug use problems, access is through a GP referral to a general mental health service or through a request for support via the ADRS if currently linked for treatment of substance use problems.

The pharmacists in the PHOENIx team obtained permissions to remotely access all possible health and social care records on outreach to understand all patients' previous health and social care history and relieve them of the burden of repeating their traumatic stories again and also for safety reasons.

In the UK, outpatient (ambulatory) management of PEH with chronic diseases takes place either solely in primary care or between primary care and hospital-based outpatient clinics. During the COVID-19 lockdowns, most outpatient appointments were switched to phone or online video consultations, which may or may not have been possible for PEH. Patients in need of urgent hospital care self-present or may be referred by their GP or others to a hospital ED from where they may be admitted to hospital or discharged back to primary care. Prescribing is undertaken by GPs and independent prescribers, for

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example pharmacists or nurses with advanced clinical skills and knowledge. All prescriptions are obtained free of charge from community pharmacies. The capacity for outreach from services that PEH use is variable across the city.

Intended purpose of the PHOENIx intervention

The PHOENIx intervention aims to decrease emergency service use and overdoses by increasing access to holistic preventative primary healthcare and improving the socioeconomic factors associated with homelessness, for example income and housing. Participants will be offered help with health and social care, including housing, for example a move from unsupported to supported accommodation; direct access to permanent housing does not form part of the intervention. Offering weekly visits, on assertive outreach and through persistent follow-up, PHOENIx aims to provide 'whole person' help for all health and social care needs: physical health, mental health, drug use problems, benefits, accommodation and social prescribing.[30–33] Access to the team for any reason was facilitated by a dedicated phone number that patients could call anytime.

The team is aware of barriers to accessing care among PEH and the problems posed by segmentation of services, so the team adopted a person-centred, trauma-informed approach. A comprehensive health and social care assessment is offered on the first meeting with each patient unless the patient's priorities take the conversation in another direction, in which case the assessment is conducted in stages thereafter. If the team is unable to provide direct health/social care help immediately, the team problem-solves with the patient on the spot, for example refer the patient or make an appointment on the patient's behalf, for example, to attend an appointment with a mental health team while booking transport and providing reminders. The team provides a variety of support at different times depending on the patient's needs, including advocacy, clothing, emotional support, phones, books, shopping and furniture.[31]

Outcomes

The coprimary endpoint is whether to progress to a definitive trial based on any improvement in the rate of presentation to ED for overdoses or other causes during the 6-month or 9-month follow-up period, as well as achievement of the following progression criteria:

- Recruitment of at least 100 patients within 4 months.
- ≥60% of patients remaining in the study at 6-month and 9-month follow-up (excluding those who have died or lost capacity).
- Establishment of the pharmacist intervention (≥60% of patients in the intervention group receiving the intervention as planned, excluding those who have died or lost capacity).
- ≥80% of patients with data collected as planned (excluding those who have died or lost capacity).

The secondary outcomes are as outlined in the following, compared between intervention and usual care groups at 6-month and 9-month follow-up:

- Healthcare utilisation, which includes the number of and the number of patients with:
  - Non-prescribed drug overdoses.
  - Hospital admissions.
  - Prescribing for multimorbidity (proportion of patients prescribed medicines for diagnosed conditions; proportion of patients with minimum doses of medicines for diagnosed conditions).
  - Contacts (phone or face-to-face) with GP/nurse/addictions worker/other healthcare professional.
  - Scottish Ambulance Service callouts.
  - Missed outpatient appointments.
- Time from randomisation until the first ED visit for overdose and other reasons, death, and hospitalisation.
- Patient-reported measures:
  - EuroQol-5D-5L quality of life score.[34]
  - Patient Experience with Treatment and Self-Management (PETS) measure.[35]
  - Frailty score.[36]
  - Anxiety/depression ratings.
  - Modified Medical Research Council (MRC) Breathlessness Scale.

Participant timeline is provided in figure 1 .

Sample size

The guidance on sample sizes for pilot studies varies, with 30–50 patients per arm thought to be sufficient because the focus is on estimating the parameters for the full study, rather than formal testing of hypotheses.[37] We aimed to invite approximately 160 patients, anticipating a recruitment rate of ~60% based on our earlier feasibility study.[32] If 100 agree to participate, we estimate the recruitment rate as 62.5% (95% CI 55% to 70%). The mortality rate in our previous feasibility study was 8.3% over 1 year; therefore, we anticipated six patients dying over 9 months.[32] Assuming a conservative retention rate of 70% after 9 months and additional losses due to mortality, we anticipate at least 64 patients with 6-month and 9-month follow-up data to inform the sample size for a full-scale RCT.

Recruitment

Researchers will visit the accommodations and other venues to approach all potentially eligible patients, face to face. Patient self-report of overdose will be confirmed by examination of clinical records and/or testimony from witnesses, for example accommodation staff, friends or injecting/drug-using partners. Confirmation included ambulance callout, naloxone administration recorded on clinical notes or in-house patient records made by the accommodation providers, or an ED visit for overdose. Researchers will ask each potential recruit about the circumstances of the overdose and when this occurred, including whether the patient had any recollection of having received any assistance from other people at the

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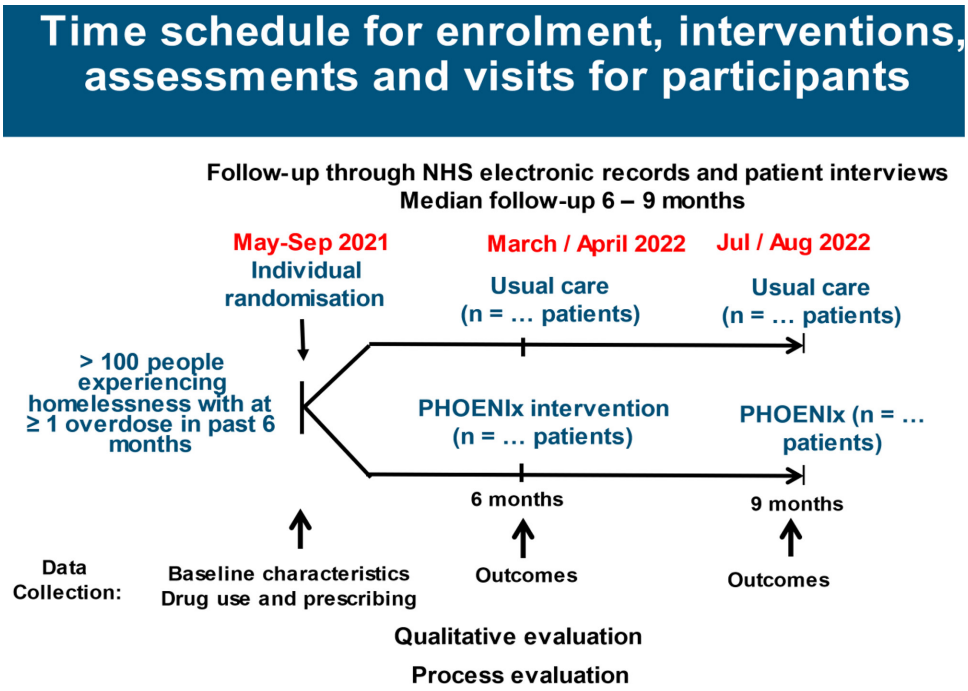

Figure 1 Participant timeline (online supplemental material). NHS, National Health Service; PHOENIx, *P*harmacist and *H*omeless *O*utreach *E*ngagement and *N*on-medical *I*ndependent prescribing R*x*.

time of overdose. The patient consent form is shown in the online supplemental material. This approach to identifying eligible patients will be taken because our collective clinical experience suggested most non-fatal overdoses are not formally recorded, or if recorded there is no standardised, identifiable coding applicable across different clinical/administrative records. Patients will be offered a non-cash incentive (voucher for use in a city centre store not selling alcohol or tobacco) of £10 (equivalent to US$13 or €12) on completion of baseline data collection and after completion of each follow-up data collection at months 6 and 9.

Assignment of interventions

Allocation: sequence generation

Staff from the University of Birmingham not directly involved in participant recruitment will remotely generate 160 sealed opaque envelopes. Each envelope will contain a folded piece of paper with the computer-generated printed words 'PHOENIx Intervention' or 'Usual care'. The envelopes will be randomly shuffled by staff from the University of Birmingham, and then will be sent in a box, by secure mail, to the Glasgow study centre before the first patient is recruited. This is an individual-level randomisation approach without stratification.

Allocation concealment mechanism and implementation

Researchers will take informed consent by discussing the patient information leaflet with the patients, explaining what the study entails and asking if they would want to participate. Some patients will read the information and make the decision themselves. In both cases, patients will have time to read the information or have it explained to them and ask questions before coming to a decision. At the end of the interview, researchers will phone the study centre asking for a randomisation. One of the research team will answer the call immediately and, in the presence of another member of the research team, pick an envelope at random from the box of envelopes. A sequential study number will be written on the outside of the chosen envelope and, in the presence of another member of the research team, while the researcher remains on the phone the envelope will be opened and the allocation revealed to the researcher (and the patient) on the phone after two members of the research team read the allocation from the piece of paper inside the envelope. Participants will therefore be randomised in a 1:1 ratio to 'usual care' or 'PHOENIx intervention'. On allocation to the intervention, the patient's details and location will be communicated to the PHOENIx team, who will be asked to contact the patient and begin offering the intervention. Following allocation to usual care, participants will have no further contact from study personnel until follow-up data collection.

Blinding

Independent statisticians conducting analysis of follow-up data will be blinded to allocation. Assessment of outcomes from clinical records will be conducted by a researcher/administrator who will be blind to assignment to the intervention or the usual care group.

Data collection, management and analysis

Baseline, 6-month and 9-month follow-up data will be collected during the researcher-led, face-to-face patient interviews in the patient's accommodation or in homeless

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charity drop-in centres in Glasgow city centre. Interviews will last approximately 45 min. Study instruments used during the interviews, for example weighing scales and peak flow metres, were familiar to the researchers. The online online supplemental material describes the baseline data to be collected on paper data collection forms during the interviews, prior to transcription into an Excel spreadsheet by the research team. These data include health and housing (if any) characteristics over time. Validated questionnaires used during the interviews have not previously been used in PEH; therefore, the research and clinical team evaluated their suitability in advance and decided only one needed modification: the PETS.[35] The section containing five questions about 'Medical and healthcare expenses' was omitted because the health service in Scotland does not charge for care and all prescriptions are free. Prescribing, comorbidities, laboratory test values, GP contacts and other healthcare utilisation data will be subsequently extracted from medical and ADRS team records and entered into the same Excel spreadsheet. We therefore plan to use data from these two sources (patient reports and data from medical records) to provide a comprehensive picture. The members of the research team will cross-check a 10% sample of data entries for accuracy and completeness.

At 6-month and 9-month follow-up, the research team will make repeated attempts to re-engage patients, as will the PHOENIx team during the intervention phase. If patients cannot be located, researchers will still be able to collect patient data from hospital records, general practices and ADRS as appropriate. If patients die or lose capacity, data up until the point of death or loss of capacity will be collected.

Statistical methods

Outcome analysis will be conducted by independent statisticians after collection of 9-month follow-up data. The primary outcome measures will be described using proportions, along with 95% CI, to describe uncertainty. Patient questionnaire and clinical measures will be analysed according to the intention-to-treat principles. Appropriate summary statistics (eg, proportions and IQR, mean and SD) along with 95% CI will be generated for study feasibility and patient-reported/clinical/health utilisation measures. By design, there is no a priori powered endpoint; however, hypothesis testing will be conducted to determine whether there is any difference between outcome measures. Between-group measures (mean differences and relative risks) will be reported with 95% CI.

Economic evaluation

An embedded economic evaluation will examine the feasibility of determining the cost-effectiveness of the PHOENIx intervention in a subsequent definitive trial. The main analysis will consider a health and social care service perspective whereby unit costs are applied to each item of health (eg, hospitalisation) and social care service use data. Unit costs will be taken from routine sources where possible, including missed appointments.[38–40] The effectiveness of the intervention will be explored in terms of health state utilities (for a future cost utility analysis), as measured using the EQ-5D-5L to generate quality-adjusted life years (QALYs) to be used alongside the cost data to give an indicative picture of cost-effectiveness. QALYs will be generated from the EQ-5D-5L using appropriate crosswalk methods and applying reference values for the EQ-5D-3L.[41–43] Both cost and utility outcomes will be quantified to describe the costs of the services and to provide QALY data, as currently few data on QALY loss associated with homelessness are available.

Qualitative evaluation

In a parallel process evaluation, we will explore participant perspectives on their drug use and overdose, including aspects of support perceived as most important, in order to prevent subsequent drug overdose, as well as their perceptions of the existing pathway for health and social care follow-up post drug overdose, together with their experience of the intervention. This will be conducted through qualitative face-to-face semistructured interviews with a purposive sample of 20–30 recruited patients in the intervention and the usual care group in order to obtain a variety of experiences. Interviews will be conducted by an independent researcher (NF) who has no knowledge of patients prior to the interviews. All interviews will be conducted in a city centre drop-in service used by PEH. Data will be gathered by recording face-to-face semi-structured interviews via a digital audio recording device and will be transcribed using pseudonyms to ensure confidentiality and anonymity. All study participants will receive a £10 voucher as recognition for their participation. Thematic coding will be conducted by NF and then checked by members of the research team to reduce the risk of bias and ensure consistency and rigour. The NPT will be used to inform conceptualisation of the process evaluation data because it is a theoretical framework used to aid development, evaluation and implementation of complex interventions. The NPT is a theory that focuses on the 'workability' of complex interventions in the real world.[44] We hypothesise that PEH may be 'overwhelmed' by self-management tasks and will vary in their capacity to cope with any given level of treatment burden depending on a range of factors, such as health literacy, language, drug-seeking behaviour, level of educational attainment, personal beliefs, physical and mental abilities, and structural and practical barriers to accessing care. This qualitative work will enable us to capture rich, complex data and unanticipated insights. Data will be analysed using NVivo V.12 software.[45]

Data monitoring

A multidisciplinary data monitoring committee involving researchers, NHS administrators and clinicians will have oversight of the qualitative and quantitative data collection processes and study methods, independent of the

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main study funder (Drug Deaths Taskforce of the Scottish Government). No interim analyses are planned, and as the study intervention is offered in addition to usual care, with PHOENIx supporting patients using guideline-based care only, adverse events of the trial intervention are not anticipated. Trial conduct will be audited by NHS GG&C Research and Development, independent of the study investigators.

Ethics and dissemination

The trial is registered with the UK Clinical Trials Registry (ISRCTN10585019) and was approved by the South East Scotland Research Ethics Committee 01. Trial results will be communicated first to participants individually, verbally or in writing, through existing homelessness networks and accommodation providers. The study findings will be described by all of the research team in accordance with the guidelines for eligibility of authorship and will be submitted for publication in a peer-reviewed journal. Suitably anonymised and summarised data will be made available on reasonable request. The principal investigator, researchers and independent statisticians will have access to the final trial data set.

Patient and public involvement

Patients were involved in the design of the study through qualitative interviews with independent researchers[33] and will be offered opportunity to discuss the findings on completion of the study. The authors also participated in a national stakeholder event to explore research priorities in healthcare for PEH.

End of study date

Processes for NHS research governance approvals were delayed during the COVID-19 lockdown, leading to a delay in the trial start date. The end of study date is on the last day of the 9-month follow-up data collection (July 2022). Allowing time for data input to the trial database, summary and analysis, the final results will be available in the last quarter of 2022.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

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