ISRCTN10585019 https://doi.org/10.1186/ISRCTN10585019

Pharmacy Homeless Outreach Engagement Non-medical Independent prescribing Rx (PHOENIx) after drug overdose for people experiencing homelessness

Submission date	**Recruitment status**	[X] Prospectively registered
16/11/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/01/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/02/2026	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

People who are homeless often have problem drug use which leads to drug overdoses. These can be either fatal or non-fatal. Non-fatal overdoses are picked up on the street, homeless accommodation, Emergency Departments and lots of other places, mostly in and around Glasgow city centre. Glasgow has a particular problem with drug use and overdoses and homelessness. People who are homeless are generally very unwell, with drug addiction being one of many problems.

Over the past 7 years a team called the PHOENIx (Pharmacy Homeless Outreach Engagement Non medical Independent prescribing Rx) comprising NHS pharmacists working in pairs with Simon Community Scotland workers, have met people who are homeless and offered an assessment of their health, drug use, housing, social activities, and benefits. The assessment is followed by the pharmacist treating the patient, referring to other services, and the Simon Community worker assessing benefits, social activities and housing, before addressing all or some of these as required.

Researchers are interested in testing whether the PHOENIx intervention can reduce the chance of people who are homeless overdosing with drugs. To do this properly, they need to run a full scale randomised controlled trial (where participants are allocated to an intervention group or usual care at random), but to enable the test to work properly, they first must check, in a miniature study, whether they can recruit and retain enough people in the trial. They also need to work out whether the intervention runs as planned and whether they can collect enough data to enable a bigger test to proceed.

Who can participate?

Adults who are homeless and have recently experienced a non-fatal drug overdose.

What does the study involve?

All participants will receive a baseline assessment from a researcher. Then participants will be allocated at random to either the intervention group or usual care. People allocated to the

intervention group will be offered weekly visits by the PHOENIx team (pharmacist and Simon Community worker) who will assess and help participants with their health, housing, benefits and social prescribing. All of this will be in addition to the care they would normally receive from their GP, nurses, hospitals, social care, voluntary sector, etc. The researchers will not be withdrawing any existing services from participants. Participants in the usual care group will receive the same level of care as usual from all of the services available in health, social and third sector agencies, but will not receive the additional offer of support from the PHOENIx team.

What are the possible benefits and risks of participating?
The PHOENIx team may help people improve their health (physical, mental and addictions) by starting them on treatments (directly or through the patient's GP/Addictions team), helping them to move into safer, better accommodation, offering activities to enable more fulfilling use of time, and help maximise benefits. There are no risks of participating.

Where is the study run from?
NHS Greater Glasgow and Clyde, Pharmacy and Prescribing Support Unit (UK)

When is the study starting and how long is it expected to run for?
November 2020 to August 2022

Who is funding the study?
The Scottish Government (Drug Deaths Task Force) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
286329

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 286329

Study information

Scientific Title
Pharmacy Homeless Outreach Engagement Non-medical Independent prescribing Rx (PHOENIx) after drug overdose for people experiencing homelessness: a pilot randomised controlled trial

Acronym
PHOENIx

Study objectives
The PHOENIx intervention reduces the risk of drug overdose in people experiencing homelessness; the pilot study examines whether the definitive trial should proceed and if so, how.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/02/2021, South East Scotland Research Ethics Committee 01 (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)7814 764 241; Sandra.Wyllie@nhslothian.scot.nhs.uk)

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Homelessness, drug overdose

Interventions
Participants are randomized using a telephone randomization service provided by the University of Birmingham

The intervention group receive weekly visits to the patient in their place of residence or other city centre low threshold venue by pharmacist/nurse independent prescriber plus simon Community Scotland outreach worker. The pair will offer an assessment of physical, mental and addiction problems followed by immediate treatment, prescription of medicines and/or referral with assertive follow up. Housing, benefits and social activities will also be assessed and referral made to a relevant agency.

The usual care group will receive the same level of care as usual from all of the services available in health, social and third sector agencies, but will not receive the additional offer of support from the PHOENIx team.

Total duration of intervention: between 6 and 9 months
Follow-up: 8-11 months after baseline assessment.

Intervention Type
Mixed

Primary outcome(s)
Current primary outcome measures as of 13/02/2024:
Achievement of criteria for progression to RCT:
1. Recruitment rate recorded as 100 participants consenting to participate by 4 months
2. Data collection: at least 80% of participants with data collected (baseline, 6 and 9 months follow up)
3. Intervention adherence: at least 60% of participants in the PHOENIx group receiving the intervention
4. Retention: at least 60% of participants remaining in the study (receiving in-person or telephone follow-up assessment at 6 and 9 months post-randomisation)
5. Improvement in the rate of presentation to Emergency Departments and overdoses collected by researchers from health and social care records at 6 or 9 months follow up

Previous primary outcome measures:
Achievement of criteria for progression to RCT: recruitment rate recorded as 100 participants consenting to participate by 4 months

Key secondary outcome(s))
Current secondary outcome measures as of 13/02/2024:
Assessed by researchers as close as possible to planned 6 and 9 months after baseline:
1. The number of participants with, and time to first, overdose or hospitalisation measured using health and social care records
2. The number of participants receiving prescribed treatment for physical or mental health and problem drug use measured using health records
3. The number of treatments per participant measured using health records
4. Health-related quality of life measured using Euro Qol-Visual Analogue Scale (EQ-VAS) which forms part of the self-rated EQ-5D-5L
5. Healthcare contacts measured using health records
6. Missed appointments measured using health records
7. Work and impact of self-management on functioning and well-being measured using the Patient Experience with Treatment and Self-management (PETS) measure
8. Number of primary health care contacts measured using clinical records
9. Number of missed and attended out-patient appointments measured using clinical records
10. Frailty measured using Fried's adapted frailty phenotype
11. Anxiety/depression measured using Patient Health Questionnaire-4 (PHQ-4)
12. Breathlessness measured using modified Medical Research Council (MRC) breathlessness scale
13. Peak flow rate measured using a peak flow meter
14. Participant-reported injecting drug use
15. Attempted suicide measured using self-report and from clinical records
16. Self-harm measured using self-report

17. Welfare entitlements measured using self-report
18. Social prescribing measured using self-report
19. Tenancy type measured using self-report

Previous secondary outcome measures:
Rate of overdose measured by collecting data from NHS Greater Glasgow and Clyde clinical records from baseline until the date of follow-up (8-11 months after baseline assessment)

Completion date
01/08/2022

Eligibility

Key inclusion criteria
1. Adult
2. Homeless
3. Drug overdose in the past 6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
128

Key exclusion criteria
Current exclusion criteria as of 13/02/2024:
1. Unable to give written informed consent
2. Living in a residential or community-based rehabilitation facility which has direct access to in-house medical and nursing care

Previous exclusion criteria:
Critically unwell/under the influence and unable to comprehend the request

Date of first enrolment
01/02/2021

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Greater Glasgow and Clyde
Glasgow City Centre
Glasgow
Scotland
G76 7AT

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
The Scottish Government (Drug Deaths Task Force) (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		16/12/2022	02/02/2026	Yes	No
Interim results article		04/04/2023	05/04/2023	Yes	No

Other publications	Perspectives on intervention	13/05/2024	02/02/2026	Yes	No
Other publications	Treatment burden	28/09/2023	02/02/2026	Yes	No
Protocol file		18/05/2022	12/08/2022	No	No