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NHS and third sector homelessness worker outreach for people experiencing homelessness, to reduce the risk of street drug overdose

Submission date
11/02/2025

Recruitment status
No longer recruiting

Registration date
20/02/2025

Overall study status
Ongoing

Last Edited
25/11/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
People are said to experience severe and multiple disadvantages (PSMD) if they are homeless, use street drugs and have been in trouble with the police. PSMD die a lot younger than people living in their own homes. A common reason is street drug overdose. They do not get many of the treatments obtained by people living in mainstream society. Untreated health conditions are bad for their health.
They tell us that supportive relationships and health care based on trust, are important to recovery. Recovery includes moving into their own homes, avoiding street drug overdoses and frequently having to go to hospital.
We aim to offer PSMD weekly visits from an NHS Pharmacist/Nurse and a Homeless Charity worker. The same Pharmacist/Nurse and charity worker will go to wherever PSMD are, offering to help with health care including prescribing, and practical and social support. By delivering this help, we aim to reduce the number of overdoses and hospital visits and improve health. We also aim to reduce criminal activity and improve quality of life. We will measure the costs of delivering this support. We will ask PSMD and staff in services how they feel about having received the visits from the Pharmacist/Nurse and charity worker.

Who can participate?
Adults who are homeless with a history of street drug overdose and criminal justice involvement

What does the study involve?
After recruiting between 300-400 PSMD, half will be allocated to receive the Pharmacist/Nurse and Homeless Charity worker visits on top of usual care. These visits will last for about 9 months. The other half will receive usual care only (without additional visits from a Pharmacist/Nurse and Homeless charity worker).
During the visits (which last about half an hour), the Pharmacist/Nurse will focus on the participant's health while the homeless charity worker will focus on the participant's wider needs e.g. stable safe place to live, welfare benefits, social activities and other practical support.

Together they will form a strong supportive, unconditional relationship to help the participant recover. They will work as part of existing NHS and Homeless charity teams in the local area.

What are the possible benefits and risks of participating?
Benefits include more contacts with a highly trained NHS clinician (Pharmacists/Nurses will be prescribers). This leads to more prescribing for health conditions that are untreated. This is expected to improve health.
Benefits also include receiving support from Homeless charity workers to speed up recovery and move out of homelessness.
Overall, people tell us the protective relationships formed through repeated visits and kindness are just as important as the actions of the NHS clinician and homelessness worker.

Where is the study run from?
Six settings in Scotland: Edinburgh, Aberdeen, Ayrshire, Lanarkshire, Dundee and Inverness

When is the study starting and how long is it expected to run for?
September 2022 to January 2027

Who is funding the study?
UK Research and Innovation (UKRI)

Who is the main contact?
Dr Richard Lowrie, Richard.lowrie@ed.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Integrated Research Application System (IRAS)
345246

Central Portfolio Management System (CPMS)

67286

Protocol serial number
UKRI 13977

Study information

Scientific Title
Pharmacy Homeless Outreach Engagement Non-medical Independent prescribing (PHOENIx) for people facing severe and multiple disadvantage: a multisite randomised controlled trial (RCT) with parallel process and economic evaluation

Acronym
PHOENIx for people facing severe and multiple disadvantage

Study objectives
Current study hypothesis as of 09/05/2025:
Prescribing pharmacists or nurses or General Practitioners working with third-sector homelessness staff on outreach, will improve health and enable People facing Severe and Multiple Disadvantages (PSMD) to undertake opportunities for vocational roles, employment, support recovery and re-integration into mainstream society.

Previous study hypothesis:
Prescribing pharmacists or nurses working with third-sector homelessness staff on outreach, will improve health and enable People facing Severe and Multiple Disadvantages (PSMD) to undertake opportunities for vocational roles, employment, support recovery and re-integration into mainstream society.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/10/2024, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224 558458; gram.nosres@nhs.scot), ref: 24/NS/0118

Primary study design
Interventional

Study design
Interventional open multicentre randomized controlled trial with parallel economic and qualitative analysis

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prevention of overdose and emergency healthcare use in people experiencing homelessness with additional severe disadvantages e.g. previous overdose and criminal justice encounters

Interventions
Participants are randomised using a telephone-based interactive voice response service through the Robertson Centre for Biostatistics.

PHOENIx outreach includes weekly visits to participants in their accommodation/other venue /street, by dedicated NHS Lothian independent prescriber pharmacists (working with GPs, Nurses and wider team at The Access Place) + dedicated Streetwork staff. Pharmacist + Streetwork staff offer help with health (including assessment, prescribing and referral) and social care (including activities, welfare benefits and advocacy), for about 9 months. This will be offered in addition to usual care.

Usual care comprises all existing services and treatments in each setting.

Intervention Type
Mixed

Primary outcome(s)
Time to first fatal/non-fatal drug overdose, with non-fatal drug overdose ascertained by self-report, a witness, or documented in health/social care/third sector case records at 9 months

Key secondary outcome(s)
Health status and healthcare use:
1. Health-related quality of life score (EQ-5D-5L, self-report)
2. Time to first, and number of emergency department attendances (from NHS records)
3. Time to, and number of ambulance call-outs (from SAS records)
4. Time to first, and number of hospital admissions (from NHS records)
5. Extent of treatment uptake for diagnosed physical & mental health problems, and problematic drug use (from NHS and Alcohol and Drug (Recovery) Service records)
6. Quantity of street drug use (self-report)
7. Number of overdoses (self-report, report by a witness, or documented in health/social care /third sector case records)
8. Rate of primary health care contacts attended and missed (from primary care NHS records)
9. Rate of out-patient clinic attendances and missed appointments (from acute sector NHS records)
10. Number of GP, Alcohol and Drug (Recovery) Service, and mental health team registrations (from NHS and Alcohol and Drug (Recovery) Service records)
11. Number of Alcohol and Drug (Recovery) Service, and mental health team attendances (from NHS and Alcohol and Drug (Recovery) Service records)
12. Number of residential drug rehabilitation stays (from rehabilitation service records)
13. Time to, and number of deaths (due to drug misuse and due to other causes) from NHS records or National Research Scotland linkage)
Scores on validated subjective measures of health from participant interviews (in person or by phone if possible):
14. Health-related quality of life (EQ-5D-5L)
15. Body Mass Index (in the normal range)
16. Blood Pressure (mmHg in normal range using NHS Scotland standards, according to clinical conditions)
17. Forced Expiratory Volume in 1 second, Forced Expiratory Volume in 6 seconds, and lung age (using COPD 6 handheld device)
18. Modified MRC breathlessness scale score (self-report, using mMRC scale)
19. PHQ4 depression and anxiety screening tool (self-report)

20. Usual number of meals per day (self-report reference: three meals per day)
21. Amount and type of exercise per week (self-report with reference to: at least 150 minutes of moderate aerobic activity or 75 minutes of vigorous aerobic activity)

Criminal justice system:
1. Time to, and number of criminal justice system contacts (criminal behaviour, criminal offending, police involvement (cautions, arrests, imprisonment, remand) from participant interviews and Police Scotland/Scottish Prison Service records

Community integration and functioning:
1. Uptake of vocational (paid or voluntary) employment or training (self-report)
2. Uptake of social prescribing opportunities (self-report)

Housing utilisation and housing support (participant report and third sector/council records):
1. Uptake of emergency/temporary accommodation (if street homeless, from housing records in third sector/self-report/housing records in local councils)
2. Duration of tenancy sustainment (from housing records in third sector/self-report/housing records in local councils)
3. Number of temporary accommodation moves (self-report/housing records [council/third sector])
4. Housing support intensity (frequency and duration of floating housing support visits) received

Welfare benefits:
1. Change the uptake of welfare benefits (number and overall value of benefits (from third sector records and self-report)

Health economic evaluation:
1. Cost per Quality Adjusted Life Year (QALY) of PHOENIx relative to standard of care in assisting PSMD, and probability PHOENIx is cost-effective at standard NICE thresholds (£20k & 30k per QALY)
2. A breakdown of the cost profile of PSMDs utilising PHOENIx vs standard of care, in terms of: health & social care utilisation; criminal justice activities; and welfare payments
3. A detailed activity-based costing of the specific PHOENIx program costs
4. Perceptions and experiences of PHOENIx from the perspectives of participants, stakeholders, and front-line PHOENIx staff

All secondary outcomes measured at 9 months (or as close as possible to 9 months) from recruitment.

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Homeless adult
2. Previous overdose
3. Previous trouble with the police

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Living in residential accommodation with 24-hour medical care
2. Posing a safety risk to self/others
3. Lacking the capacity to consent (although if due to intoxication, researchers may offer recruitment at a later date)

Date of first enrolment
12/02/2025

Date of final enrolment
25/06/2025

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Edinburgh
-
Edinburgh
Scotland
EH8 9AG

Study participating centre

Inverness
-
Inverness
Scotland
IV2 3BW

Study participating centre
Dundee
-
Dundee
Scotland
DD1 9SY

Study participating centre
Ayrshire
-
-
Scotland
KA6 6AB

Study participating centre
Aberdeen
-
Aberdeen
Scotland
AB15 6RE

Study participating centre
Lanarkshire
-
-
Scotland
G71 8BB

Sponsor information

Organisation
NHS Lothian ACCORD

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Richard Lowrie (richard.lowrie@ed.ac.uk).
The type of data that will be shared: summary quantitative data depending on the request.
Dates of availability: from the end of January 2027 depending on reasonable request.

IPD sharing plan summary
Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/11/2025	25/11/2025	Yes	No