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PHOENIx community pharmacy trial

Submission date
16/06/2022

Recruitment status
No longer recruiting

Registration date
18/07/2022

Overall study status
Completed

Last Edited
21/10/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Persons experiencing homelessness are among the most marginalised, destitute and vulnerable groups in the UK. Despite most homeless persons being aged in their late 30s, most have seven different health problems. This is on a par with people aged 85 years old living in their own homes. Most homeless persons die before they reach 43 years of age and many deaths are preventable if they receive care but homeless persons find it difficult, amidst all their competing needs, to seek help until it is too late.

Most health services operate by appointment, in buildings, whereas homeless persons are displaced and live on the streets, in soup kitchens and temporary accommodation, far from their GP, addictions team and/or mental health team, leading to fragmented care. Health conditions often remain underdiagnosed, and untreated and they drop out of care unintentionally, because of their chaotic circumstances. Drug overdose, a repeated cycle of homelessness, and high use of emergency departments are common. There is not enough evidence for us to make informed changes to health services for people who are homeless, so we plan to test a new approach involving pharmacists and third-sector homeless charity workers collaborating, in city centre community pharmacies.

Community pharmacies are often used by homeless persons daily for services such as their prescriptions and treatment for problem drug use. There is no need for appointments and they are located in city centres, where people who are homeless call home. However, the clinical skills and knowledge of pharmacists including prescribing roles (they can prescribe medicines) have not been formally tested in community pharmacies, caring for homeless persons. Charities help people who are homeless, by acting as advocates, helping with benefits, housing, shelter, food and clothing. Street-based charities have outreach workers with lived experience of homelessness, who develop strong relationships and trust with people who are homeless. They operate separately and do not formally share information with the health service leading to missed opportunities.

Who can participate?
Homeless adults who are service users of one of the designated community pharmacies

What does the study involve?
In this study, we are testing a new model of care that offers integrated health and social care

support for people experiencing homelessness. A pharmacist prescriber will work in partnership with a third-sector charity worker, in community pharmacies. Development work shows our intervention is received well by patients, in Glasgow (Pharmacy Homeless Outreach Engagement Non-medical Independent prescribing Rx -PHOENIx) where the pharmacist deals with health and charity worker deals with housing, benefits, and social prescribing. It helps people get onto treatments for their physical, and mental health and addictions. Now we would like to see whether it works by testing the approach in a controlled way, and see if it is value for money, by running a miniature controlled trial. This will prepare us for a much bigger trial that will give us conclusive results, influence policy decisions, roll out the intervention across the UK, and improve the health of people who are homeless, which is long overdue.

We aim to share our findings with the homeless persons and staff, in medical journals, and in national scientific meetings and will make these available through websites of professional societies, government bodies and homeless charities. Our charity co-applicant partners will disseminate in their networks.

What are the possible benefits and risks of participating?
In the future, this study could help improve care for people who are experiencing homelessness. Participants in the intervention group will receive additional follow-up care, which they may not normally receive. Information we get from this study will help us plan a larger study to test how effective the PHOENIx intervention is, and whether it improves the quality of life.

We do not anticipate any disadvantages to participants taking part. They will need to give their time to participate in the study including completing questionnaires when they join the study and at three and six months. There is a potential that the interview may be tiring or the topics may be challenging. However, participants will be able to take a break or stop the interview at any point. If the researcher becomes concerned for the participant's wellbeing during the interview, they will discuss their concerns with you and work in partnership with the participant to determine the best course of action. If necessary, the researcher may contact participants' GPs if they are concerned about participant wellbeing. Participants will be informed that taking part in the study and any answers they give in questionnaires or interviews will not affect their treatment in the NHS, their care or their legal rights.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
March 2022 to January 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Sarah Tearne, s.clarke.2@bham.ac.uk

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309760

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52971, IRAS 309760, RG_20-123123

Study information

Scientific Title
Pharmacy Homeless Outreach Engagement Non-medical Independent prescribing Rx (PHOENIx) community pharmacy-based pilot randomised controlled trial

Acronym
PHOENIx community pharmacy

Study objectives
To test the hypothesis that a pilot study of the PHOENIx intervention shows merit in progression to a definitive randomised controlled trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/07/2022, East Midlands - Leicester South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8193, +44 (0)207 104 8177; leicestersouth.rec@hra.nhs.uk), ref: 22/EM/0119

Study design
Randomized multicentre open-label parallel-group external pilot trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community, Pharmacy

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Persons experiencing homelessness

Interventions

In addition to usual care, the PHOENIx team (pharmacist independent prescriber in partnership with a third sector charity worker) will assess the participants' physical, mental and addictions health, housing, benefits and social activities during a consultation in the community pharmacy. Taking approximately one hour, face to face (with full personal protective equipment), the PHOENIx team will record the participant's priorities, and going at the participant's pace, will assess, treat, prescribe, and refer to other health and social care teams.

Intervention Type
Mixed

Primary outcome measure
1. The randomisation process and recruitment rate measured by the numbers invited to participate, numbers recruited at baseline
2. Retention of those remaining in the trial at 3 months and 6 months follow up
3. Adherence to the intervention measured by the proportion of participants attending the intervention at planned visits
4. Proportion of participants with patient-reported outcomes completed measured by the number of participants who complete the questionnaire booklet at planned visits
5. Proportion of participants with routinely collected Emergency Department visits and mortality data available at 6 months

Secondary outcome measures
Clinical measures:
1. Number and cause of Emergency Department visits measured by patient-reported and routinely collected data at 3 and 6 months
2. Number and cause of primary care general practice visits measured by patient-reported and routinely collected data at 3 and 6 months
3. Mortality measured by routinely collected data at 6 months
4. Medication changes (prescribed) and taken (in the case of opioid substitution therapy where supervised) measured through patient-reported and routinely collected data at 3 and 6 months
5. Number and cause of hospitalisation measured by patient-reported and routinely collected data at 3 and 6 months
6. Intervention acceptability measured by qualitative interviews with patients, the intervention delivery team and stakeholders as an ongoing process evaluation
7. Generic health-related quality of life score and health thermometer score measured by EQ-5D-5L at 3 months and 6 months
8. Frailty measured by Fried's adapted frailty phenotype at 3 months and 6 months
9. Respiratory health measured by Peak Expiratory Flow Rate, MRC Dyspnoea scale and COPD Assessment Test (CAT) at 3 months and 6 months
10. Blood pressure measured by blood pressure monitors at 3 months and 6 months

Addiction measures:
1. Number of participants experiencing drug overdoses not requiring an Emergency Department visit and the number of overdoses measured by patient-reported data at 3 months and 6 months
2. Number of participants (and number of times) referred to drug and alcohol services, rehab, mental health and GP, and the numbers attending subsequently measured by patient-reported and routinely collected data at 3 and 6 months
3. Numbers and time to commencement on opiate substitute treatment (OST)/benzodiazepine /heroin-assisted treatment and collecting ≥ 80% of daily doses measured by routinely collected data at 3 months and 6 months
4. Number of participants treated with and time to minimum therapeutic OST dose measured by

routinely collected data at 3 months and 6 months
5. Dose of OST measured by routinely collected data at 3 months and 6 months
6. Number of missed appointments (with any team, including irregular discharges) and number of participants with missed appointments measured by routinely collected data at 3 months and 6 months
7. Number of persons and days in prison/criminal justice encounters measured by patient-reported data at 3 and 6 months

Social measures:
1. Housing tenure including night shelters, emergency accommodation measured by self-reported data and those provided by the council or third sector, or care home at 3 months and 6 months
2. Level of debt as self-reported by patients at 3 months and 6 months
3. Criminal justice encounters as self-reported by patients at 3 months and 6 months

Overall study start date
01/03/2022

Completion date
01/01/2024

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Experiencing homelessness including:
2.1. Rooflessness
2.2. Houselessness
2.3. Insecure or inadequate housing as per the ETHOS typology
2.4. Staying in homeless shelters
2.5. Rough sleeping
2.6. Staying in temporary accommodation, such as bed and breakfasts (B&Bs), hostels, squats; or that sofa surfing between family and friends' houses
3. Attending or service users of one of the designated community pharmacies

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. Living in accommodation with 24-hour support which includes in-house medical care
2. Intoxicated or (in the opinion of the researcher) posing a safety risk to staff and lacking the capacity to consent

Date of first enrolment
21/07/2022

Date of final enrolment
01/10/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
NHS Greater Glasgow and Clyde
J B Russell House
Gartnavel Royal Hospital
1055 Great Western Road Glasgow
Glasgow
United Kingdom
G12 0XH

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
Unit 1
50 Summer Hill Road
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United Kingdom
B1 3RB

Sponsor information

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Sponsor type
University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. A final study report to be shared with the funder
2. The report will also be available on the study website
3. Pilot study results will be shared with relevant stakeholders with the aim of further engagement and support for the main study

Intention to publish date

01/01/2025

Individual participant data (IPD) sharing plan

Requests for data generated during this study will be considered by the University of Birmingham Clinical Trials Unit (BCTU). Data will typically be available 6 months after the primary publication unless it is not possible to share the data (for example the trial results are to be used as part of a regulatory submission, and the release of the data is subject to the approval of a third party who withholds their consent, or BCTU is not the controller of the data).

Only scientifically sound proposals from appropriately qualified Research Groups will be considered for data sharing. The request will be reviewed by the BCTU Data Sharing Committee in discussion with the clinical investigators (CIs) and, where appropriate (or in absence of the CIs) any of the following: the Trial Sponsor, the relevant Trial Management Group (TMG), and independent TOC.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/02/2023	24/02/2023	Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/10/2024	21/10/2024	Yes	No