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iHOST (Improving Hospital Opioid Substitution Therapy): An intervention to improve care for people who use opioids in NHS hospitals

Submission date
04/07/2022

Recruitment status
No longer recruiting

Registration date
11/07/2022

Overall study status
Ongoing

Last Edited
05/06/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People who use illicit opioids (PWUO), such as heroin, are over-represented in urgent and emergency admissions. Late presentation with complications from injecting-related infections and injuries is common, yet retention in hospital care is low. This is a serious problem, associated with: reliance on ambulatory care, complex admissions, unplanned hospitalisation, discharge against medical advice (DAMA), readmission, surgical intervention and high NHS costs.
Our research, engagement with affected groups, and international evidence show that poor management of opioid substitution treatment (OST) in hospital emergency, acute admissions and high burden wards is a primary barrier to timely and effective care for PWUO. Experiences of OST delay or omission can cause severe physical and psychological distress and result in treatment interruption or DAMA to obtain illicit drugs. PWUO experiencing opioid withdrawal can be challenging to manage; improving their experience and feelings of safety in the hospital setting is beneficial for both patients and providers.
Aim: To optimise OST management in hospital settings to reduce delayed presentation, self-discharge and emergency readmission among PWUO.

Who can participate?
People who use opioids (PWUO): People who have a history of opioid use for non-medical reasons AND/OR are prescribed OST in a community setting for illicit opioid dependence; 18 years or over; assessed as capable to consent (not in debilitating withdrawal or intoxicated); presenting at A&E, an acute admissions ward or inpatient at one of the hospital sites OR a client at one of the linked drug treatment services.
Providers: healthcare staff involved in the prescribing, supply or administration of medicines to patients within A&E, acute admissions and high burden inpatient wards; staff at linked drug treatment services.

What does the study involve?
There are four phases to this study. Phase 1: Finalising the iHOST intervention; Phase 2: Testing iHOST (at University College London Hospital); Phase 3: Evaluating iHOST (at St James's University Hospital, Leeds and Royal Stoke University Hospital, Staffordshire); Phase 4:

Developing iHOST resources and outputs.
Our primary outcomes will be measured through a difference-in-difference analysis of routinely collected clinical data at three iHOST evaluation sites, using comparative data from the national Hospital Episode Statistics (HES) database. A qualitative process evaluation, involving in-depth interviews and focus groups with patients and providers will assess iHOST acceptability and fidelity, clarify causal mechanisms, and identify contextual factors such as human resources and commissioning that might be associated with success.
Full methods details are available in section A13 of the IRAS form and in the project protocol.

What are the possible benefits and risks of participating?
Qualitative interview and focus group participants might not directly benefit from this research, but our aim is that this intervention will help improve hospital care for people who use drugs. This might be of benefit to patient and provider participants and/or their peers and colleagues in the future.
Being a participant in the study should not involve any physical or psychological harm. We recognize that talking about care seeking and possible experiences of stigma due to opioid use can be difficult for some and that the potential risk of pre-existing stigma and prejudice can be a barrier to research engagement by PWUO and staff. We mitigate this risk firstly, by engaging PWUO through our peer researchers. PI Harris has over 17 years' experience in research with PWUO and Noctor is an experienced peer outreach worker. Both have strong track records of developing trusting research relationships with people from marginalised communities.
Secondly, we will also use a peer model to engage staff: the 'iHOST champion'. We are working closely with a research nurse in Phase 1 to develop this role description with the aim of promoting sustainability. Staff turn-over has here been identified as a risk. The voluntary nature of the training offer is a risk to uptake. The champion model is designed to promote engagement, which will be badged as contributing to continuing professional development and staff will receive a certificate from Exchange Supplies on completion to evidence CPD

Where is the study run from?
London School of Hygiene and Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
March 2022 to May 2026

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

Who is the main contact?
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Study website
https://www.lshtm.ac.uk/research/centres-projects-groups/ihost

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
310856

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52950, NIHR133022, IRAS 310856

Study information

Scientific Title
Improving Hospital Opioid Substitution Therapy (iHOST): implementation and assessment of an intervention to reduce late presentations, discharges against medical advice and repeat admissions among people who use opioids

Acronym
iHOST

Study objectives
Does the iHOST toolkit reduce delays in OST prescription in two hospitals compared to historical local data, and does this lead to reduced DAMA and emergency readmission of PWUO compared to historical local rates and a national comparator cohort?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/05/2022, London - Camden & Kings Cross Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +442071048276; camdenandkingscross.rec@hra.nhs.uk), ref: 22/LO/0370

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Addiction, substance dependence

Interventions
The iHOST toolkit comprises:
1. A 'My Meds' card. A prototype card has been developed with people who use opioids (PWUO). This provides information for hospital staff to prioritise and expedite medicines reconciliation, including blank fields for OST prescriber and pharmacy contacts.
2. A helpline for patients and providers run by the charity Release.
3. An online training module for staff in hospital Accident and Emergency (A&E,), acute admissions, and high burden hospital wards.
4. A 'best practice' hospital policy template.
5. An iHOST 'champion' to support sustainability post intervention.

This is a four-phase study. Methods for each phase, including research participant involvement are outlined below:
Phase 1 [months 1-8]: iHOST OPTIMISATION. Sites: UCLH, linked drug treatment services.
A. Evidence review: We will conduct a systematic review of the literature to synthesise the evidence for interventions for managing the care of people who inject drugs in emergency outpatient or acute hospital inpatient settings. We have conducted a review of NHS policies for substance dependence management. This will be finalised for publication.
B. iHOST toolkit optimisation.
- We will conduct 2 workshops with PWUO and providers, 1 at each of two drug treatment services (Margarete Centre, Camden and Islington NHS Trust and Better Lives, Islington) to receive feedback on and finalise the My Meds card design and seek input into the Advocacy helpline concept (acceptability and content need). Participants: ~7 PWUO & 3 providers per workshop, n=~20.
- We will conduct 1 workshop at UCLH to inform training module content and design. Participants: UCLH A&E, acute admissions, high burden wards, drug liaison; hospital pharmacy staff (n=~10).
- We will conduct 1 additional workshop at Release Charity, as required, to finalise advocacy helpline content, delivery and methods of data generation. Participants: Release staff (n=4); PWUO (n=6); Hospital providers (n=4).
- We will employ Delphi methods to develop and finalise the NHS hospital substance dependence management policy template. These comprise developing evidence statements for

each section of the hospital policy template (derived from literature review and national clinical guidance) alongside 'best practice' examples from our policy review to be sent to a panel of experts (comprising the lead pharmacist for each UK drug treatment service, members of the Specialist Pharmacy Service, the UK clinical guidelines panel, lead clinicians and PPI representatives) to obtain their views and arrive at a consensus.
- We will work with a part time research nurse employed for the study at UCLH to develop a 'iHOST champion' role description and think more broadly about how iHOST implementation can be supported to be sustainable within the complex culture of the hospital system in the long term.
C. Patient involvement set up and workshops. We will work with a group of people with lived experience of opioid use (including being on OST) over the course of the study to seek input into and assess the acceptability of participant information materials, study methodology, findings interpretation and dissemination plans. We aim also to develop a 'cultural safety' framework with this group over the 36 months, drawing on findings from the process evaluation to understand what PWUO require to feel safe in hospital spaces and how providers and systems can change to facilitate equitable care. We will hold 4-6 workshops with a core group of PWUO (6-8), some of whom have already worked with the PI on previous studies and expressed an interest in participating. We will recruit additional members
(n=2-3) to ensure participant diversity, particularly in relation to gender.

Phase 2 [months 9-14] Test feasibility. Sites: UCLH, JSUH, RSUH and linked drug treatment services.
A. Embed and test iHOST toolkit:
- We will attend a staff meeting at each drug service local to UCLH to present the iHOST concept. We will provide a stock of MY Meds cards to each service for distribution to their clients. We will assess the acceptability of conducting observations of My Meds provision at the drug treatment services and arrange researcher visits if feasible.
- If appropriate we will conduct non-participant observations of My Meds card provision in the DTS and use at UCLH to assess acceptability and iHOST implementation fidelity (n=~16 separate observations).
- We will conduct non-participant observations of 'iHOST champion' interactions with UCLH staff to assess the acceptability and impact of methods to sensitise staff to the iHOST concept and toolkit. (n=~8 observations/occasions).
- We will conduct in-depth interviews with 6 inpatient PWUO, 6 community based PWUO, 4 hospital staff, 4 drug treatment staff (n=20 total) to explore iHOST acceptability, impact on practice, contextual barriers and facilitators to implementation. Participants for qualitative interviews will be asked to fill in a brief form with demographic information, prior to the interview starting and after providing informed consent. This will not include personal participant identifers (an ID number only) and will enable us to ascertain diversity across the sample and provide an additional check regarding eligibility criteria. Interviews will be audio-recorded with consent and conducted in a private room at the recruiting service.
B. Evaluate feasibility of outcome measures at UCLH.
- We will work with a data scientist at UCLH, employed part time for the study, to compare clinical outcomes on the EPIC database before and after implementation of iHOST. These include process-related measures such as time from admission to provision of OST, and outcome-related measures such as the risk of DAMA.
- We will conduct a controlled analysis of changes in two outcomes (DAMA and 28-day readmission) between UCLH and other hospitals across England, using Health Episodes Statistics (HES) database.
C. Prepare for phase 3 implementation and evaluation.
- We will hold two workshops with PWOU and providers at the same DTS as in phase 1 (Margarete centre and Better Lives) to discuss findings, assess and collaboratively refine

intervention components. Participants: 8 providers & 12 PWUO, n=20.
- We will work with hospital site data scientists (time costed) to review the clinical information systems at the hospitals and refine analysis plans if necessary.
- We will conduct 4 focus groups, one at each of two drug treatment services (Staffordshire Humankind, Forward Leeds) and one at each linked hospital site (SJUH, RSUH) to explore local context, iHOST expectations and perceived quality of collaborative relationships between drug treatment and hospital services. Participants: drug treatment service FG = 14 PWUO & 6 providers, n=20; hospital FG = drug treatment liaison team, nurses on high burden wards & affiliated staff, n=16.

Phase 3 [months 15-29]: Evaluation. Sites: JSUH, RSUH and linked drug treatment services.
A. Embed iHOST toolkit at evaluation sites
- We will distribute 'My Meds' cards and promotional materials to Staffordshire Humankind, Forward Leeds and any other DTS proximal to the hospital evaluation sites.
- Work with JSUH and RSUH clinical leads to promote and fill the iHOST champion role.
- Liaise with lead clinicians and iHOST champions to will coordinate training set up, staff sensitisation and training promotion.
B. Quantitative evaluation
- We will employ a difference-in-difference method to measuring patient outcomes in two groups (iHOST sites and control hospitals) at two points in time. At the first point in time, both groups are unexposed (i.e. iHOST is not implemented). At the second point in time, iHOST is implemented at iHOST sites only. The design is based on comparing the change in outcomes. Control data will be generated from the Hospital Episode Statistics database and iHOST data from local hospital database systems (such as EPIC).
- We will assess the acceptability, reach and perceived impacts of staff training activities through analysis of selfcomplete survey data embedded into the training platform (n=~150 staff).
- We will ask Drug Treatment Services to keep a record, where possible, of My Meds card uptake among service users and Release to record helpline call numbers. These anonymised data will be assessed to inform measures of iHOST reach.
- All costs associated with iHOST will be mapped and categorised. Using results from clinical data review, we will perform a cost-consequences analysis assessing the comparative intervention and hospital costs and outcomes associated with providing and not providing iHOST over the study period. Hospital episodes will be costed using NHS Reference Costs, whereas NHS staff time will be costed using information from the Personal Social Services Research Unit (PSSRU).
C. Qualitative process evaluation
- We will conduct a process evaluation at both intervention sites to assess iHOST acceptability, perceived impact on practice, barriers and facilitators to implementation and uptake and contextual and un/anticipated mechanisms of change. Methods comprise:
- In-depth interviews with 8 PWUO and 6 providers at 4 sites (n=32 PWUO; 24 providers): the 2 intervention hospitals and 2 linked drug treatment services.
- Observations of iHOST delivery at each site and at the linked DTS. We will develop an observation tool/template comprising categories identified in phase 1 (for example, types and frequency of patient provider interactions, use of the My Meds card, management and recording of DAMA). Fieldnotes will also be taken of observations (narrative accounts). No audio recordings will take place during observations and no names or identifiers will be included in fieldnotes.
D. PPI / logic model and theory development
- At the end of each phase we will hold a workshop with our PPI group, to feedback findings to date and collaboratively develop our logic model and cultural safety framework.

Phase 4 [months 29-36]: Dissemination. Sites UCLH, JSUH, RSUH and linked drug treatment services.

A. Co-produce final iHOST toolkit
- We will hold a co-production workshop at each site (n= 3, London, Staffordshire, Leeds) to disseminate findings, consolidate lessons, co-produce & finalise outputs with 18 PWUO & 12 providers (n=30)
- In collaboration with Exchange Supplies, our Advisory Board and PPI group we will finalise protocols and/or hard copies of card, helpline, policy template and training module for dissemination; develop an implementation toolkit for dissemination of iHOST to other NHS trusts and online live webinar training and slide-sets to accompany the toolkit targeted at commissioners, drug treatment providers, hospital consultants, A&E, pharmacy and high burden wards.
B. Multi-disciplinary dissemination and policy advocacy
- We will produce a policy-orientated health service delivery report and disseminate findings, and policy advocacy through meetings and webinars involving UK Health Security Agency and Office for Health Improvement and Disparities; National Drug Treatment Providers; Specialist Pharmacy Service; NHS England, Royal College of General Practitioners; ICS commissioners; Royal Pharmaceutical Society; College of Mental Health Pharmacy and Royal College of Psychiatrists.
- Working with our PPI group we will co-produce a resource aimed at people who use drugs, to be designed by Linnell publications

Intervention Type
Other

Primary outcome measure
Measured using patient records:
1. Discharge against medical advice (measured at hospital discharge)
2. Emergency readmission at any hospital in England (measured in the 28 days after discharge).

Secondary outcome measures
Measured using patient records:
1. Provision of opioid substitution therapy (OST)
2. Dose of OST
3. Duration between admission and provision of OST
4. Records of illicit substance use while admitted to hospital

Overall study start date
01/03/2022

Completion date
31/05/2026

Eligibility

Key inclusion criteria
PWUO:
1. People who have a history of opioid use for non-medical reasons AND/OR are prescribed OST in a community setting for illicit opioid dependence
2. Aged 18 years or over
3. Assessed as capable to consent (not in debilitating withdrawal or intoxicated)
4. Presenting at A&E, an acute admissions ward or inpatient at one of the hospital sites OR a client at one of the linked drug treatment services

Providers:
1. Healthcare staff involved in the prescribing, supply or administration of medicines to patients within A&E, acute admissions and high-burden inpatient wards
2. Staff at linked drug treatment services

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 746; UK Sample Size: 746

Key exclusion criteria
1. People who are under 18 years of age
2. In secure services
3. Lacking capacity for informed consent
4. No history of opioid dependence
5. (For providers) are not involved in OST-related service provision

Date of first enrolment
01/11/2022

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London Hospitals NHS Foundation Trust
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
St James's University Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

Sponsor details
Keppel Street
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Sponsor type
Hospital/treatment centre

Website
http://www.lshtm.ac.uk/

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan
1. The iHOST toolkit
• The staff training module will be hosted on the Exchange Supplies training platform. It will be free to access by NHS staff, and contribute to CPD. We will seek to have this endorsed by NICE
• iHOST champion role description and resource pack for NHS Trusts.
• My Meds card template, purchase and information links for drug treatment services /commissioners
• Policy framework template and best practice guidelines for OST provision in secondary care settings.
• Dedicated patient and provider OST helpline, incorporated in Release's advocacy support services.
2. Cultural safety framework developed with PWUO over the research duration.
3. Peer-reviewed publications (systematic review, protocol, policy review paper, > 3 findings papers)
4. Articles in publications aimed at: addiction specialists; healthcare providers and PWUO.
5. Resource designed by Linnell publications, informed by PPI and targeted toward PWUO.
6. International and national conference presentations.
7. Full study report detailing the research, findings and its policy, managerial and practice implications.
8. Project blog/website and Twitter account to disseminate lay information about the study.

Intention to publish date
31/05/2027

Individual participant data (IPD) sharing plan
Researchers can apply to NHS Digital to use this resource using the DARS service (https://digital.nhs.uk/services/data-access-request-service-dars). The data are not publicly available to protect patient confidentiality.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3	04/02/2022	11/07/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		18/11/2024	05/12/2024	Yes	No