ISRCTN33965312 https://doi.org/10.1186/ISRCTN33965312

Telephone-delivered incentives for encouraging individuals receiving opiate treatment to attend their pharmacy to take their medication: testing the feasibility of undertaking a future trial

Submission date
14/06/2023

Recruitment status
No longer recruiting

Registration date
26/06/2023

Overall study status
Completed

Last Edited
06/02/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Most people treated for heroin addiction are prescribed methadone or buprenorphine to help them to stop using heroin safely and avoid withdrawal. If people do not take these medications as directed, they may be asked to take a daily dose under a pharmacist's supervision. Supervision ensures patients take their prescribed dose every day and prevents diversion and overdose. If a patient misses their dose, they will experience opiate withdrawal and may crave heroin. If they miss three daily doses, people lose their tolerance to the drug and risk overdosing. Unfortunately, many patients miss their doses and pharmacists do not always let their doctors know. Research suggests financial incentives might improve medication adherence. Researchers have developed technology which delivers financial incentives using mobile telephones and automatically alerts doctors when doses are missed. The study aims to understand if it's feasible to conduct research to test whether financial incentives, delivered by mobile phone, encourage patients to take prescribed medication under community pharmacist supervision.

Who can participate?
Anyone aged 18 years and over who has missed three doses of supervised OAT and is re-presenting at the drug clinic for dose assessment/re-start

What does the study involve?
The researchers will investigate the feasibility of conducting a trial to evaluate whether the intervention increases supervised methadone or buprenorphine consumption at pharmacies. Three drug services (each with seven allied pharmacies) will be recruited and randomly offered one of three approaches. Some patients will receive telephone-delivered incentives (via text), others an appointment reminder (text), while others receive no texts. The researchers will assess the acceptability of these approaches, how recruitment works and whether they can track patients to measure their outcomes.

What are the possible benefits and risks of participating?
Service users will have a chance to receive small financial incentives for attending their pharmacy to take their methadone or receive reminders. Involvement in the research may improve treatment-related outcomes for service users and improve the way they receive their medication.
There are no risks of taking part. Participants will be asked to log their visits to the pharmacy onto the system via the tablet at the pharmacy counter. This will only take a couple of minutes.

Where is the study run from?
The study is being conducted by King's College London in collaboration with South London and Maudsley NHS Trust and Turning Point (UK)

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

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

Who is the main contact?
Dr Nicola Metrebian, nicola.metrebian@kcl.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
321647

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 56111, IRAS 321647

Study information

Scientific Title
Mobile telephone contingency management to encourage adherence to supervised medication among individuals receiving opioid agonist treatment: a feasibility study (TIES2)

Acronym
TIES2

Study objectives
The study's aim is to assess the feasibility of conducting a future confirmatory trial to assess the clinical and cost-effectiveness of mCM to encourage adherence with supervised methadone /buprenorphine in community pharmacies.

Specific objectives include:
1. To assess the number of eligible patients, rates of recruitment and recruitment procedures.
2. To assess the acceptability of the study to patients not receiving incentives (mR and TAU arms).
3. To test the accuracy of recording attendance at the pharmacy via self-login among participants not receiving incentives (mR and TAU).
4. To assess the utility and practicality of different options for quantifying the primary outcome measure (adherence to medication).
5. To characterise aspects of the primary outcome needed for a sample size calculation for a larger trial (including an estimate of the intraclass correlation).
6. To assess participant and clinician perspectives on our modified eligibility criteria.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/05/2023, West Midlands - Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8010 ; blackcountry.rec@hra.nhs.uk), ref: 23/WM/0098

Study design
Randomized; Interventional; Design type: Treatment, Device, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Individuals receiving opioid agonist treatment

Interventions
The researchers will recruit three drug services (one or two from South London and the Maudsley NHS Foundation Trust (SLaM) and one or two from a large non-NHS service provider (Turning Point). Drug services will be eligible if they are providing opiate agonist treatment (OAT; methadone or buprenorphine) and supervised consumption at community pharmacies. This feasibility study will use a cluster randomised design, where each drug service (and its allied community pharmacies) forms a cluster. Within each cluster, participants will receive the same allocated condition. Participants will receive supervised methadone or buprenorphine at a participating community pharmacy during a 12-week treatment period. OAT will be delivered in line with existing service protocols at sites. Participants will record their attendance at their pharmacy via a tablet computer to indicate they have taken their supervised medication.

Drug services (each with up to seven allied community pharmacies) will be allocated (1:1:1) to deliver one of the following interventions outlined below:
1. mCM: using text messages to deliver Contingency Management (n=20). Each time a participant attends their pharmacy and consumes their supervised medication they will be sent a text message giving positive reinforcement (praise) and earn a small financial reward of £1. If they attend for 6 days consecutively, they will earn a bonus reward of £5. The total possible financial reward is £11/week. Participants will be paid directly through 'Bread4Business' pre-paid debit cards. If they do not attend, participants will be sent a “feedback message” informing them that they have not earned the incentive.
2. mR: using text messages to deliver reminders (n = 20). Participants will be sent text message reminders to attend the pharmacy and take their supervised medication.
3. TAU: treatment as usual (n = 20)

Participants will not be sent any text messages and will continue to receive treatment as usual.

In mCM and mR, weekly reports of adherence and alerts of missed doses will be sent to prescribers.

Intervention Type

Other

Phase
Not Specified

Primary outcome(s)
The primary feasibility outcome is the number of eligible patients enrolled per week over the 12-week recruitment period (assessed using recruitment records; pre-baseline).

Key secondary outcome(s))
1. Percentage of screened patients eligible for inclusion and reasons for ineligibility (assessed from screening forms; pre-baseline).
2. Percentage of eligible patients who consent to participate and reasons for refused consent (assessed from screening forms; pre-baseline)
3. Adherence to telephone system based on matches between self-login at pharmacy and dispensing records (N days where these match/N days total) (assessed from phone system database; continuously during 12-week follow-up).
4. Number/percentage attending follow-up interview (assessed at follow-up interview at 12 weeks).
5. Number/percentage of weeks on supervised consumption during 12-week intervention (assessed from phone system database over 12-week intervention period; and pharmacy records at end of intervention period).
6. Number/percentage on supervised consumption at end of 12-week intervention period (assessed from phone system database at 12 weeks; and pharmacy records at end of intervention period).
7. Number of restarts during 12-week intervention period (where a participant misses >3 appointments and needs to re-present at the clinic to restart their prescription) (assessed from phone system database and pharmacy records extracted at 12 weeks).
8. Number of days from last dose (i.e., last attendance at supervised consumption appointment) until prescription restart (assessed from phone system database and pharmacy records extracted at 12 weeks)
9. Qualitative assessment of clinician perspectives on the revised eligibility criteria (assessed via interviews at 12-14 weeks).

Completion date
30/09/2024

Eligibility

Key inclusion criteria
The eligibility criteria for enrolling service user participants will include:
1. Receiving supervised OAT (methadone or buprenorphine) 6 days a week
2. Missed three doses of OAT and re-presenting at drug clinic for dose assessment/re-start
3. Aged ≥18 years at time of enrolment
4. Attending a participating pharmacy
5. Owns a mobile phone
6. Able to read English and not require the service of an interpreter
7. Willing and able to provide informed consent.

The criteria for enrolling community pharmacies will include:
1. The pharmacy is currently providing supervised consumption of oral methadone or

buprenorphine to the patients at the drug clinic
2. Pharmacists are willing and able to provide six days of supervised consumption of oral methadone or buprenorphine
3. The pharmacy has a consultation room on the premises or a separate designated area on the dispensing counter where participants can consume their oral methadone or buprenorphine under supervision
4. The pharmacy is willing and able to provide dispensing records for participants over the 12-week intervention period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients who cannot read English AND require the service of an interpreter to understand a brief oral description of the study

Date of first enrolment
23/08/2023

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lorraine Hewitt House Drug & Alcohol Service
12-14 Brighton Terrace
Brixton
United Kingdom
SW9 8DG

Study participating centre
Wandsworth Drug & Alcohol Service
162 St. John's Hill
Upper Tooting
London
United Kingdom
SW11 1SW

Study participating centre
City & Hackney Turning Point Drug & Alcohol Service
102-110 Mare Street
Hackney
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E8 3SG

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR204088

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository: King’s Open Research Data System (KORDS)

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes