

# 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

<b>Submission date</b> 14/06/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/06/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/02/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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](mailto:nicola.metrebian@kcl.ac.uk)

## Contact information

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Principal Investigator

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

321647

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Other

## **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**

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 measure**

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).

### **Secondary outcome measures**

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).

### **Overall study start date**

01/03/2022

### **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  $\geq 18$  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

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

Planned Sample Size: 60; UK Sample Size: 60

## **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**

England

United Kingdom

**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

London

United Kingdom

E8 3SG

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**Organisation**

King's College London

**Sponsor details**

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**Sponsor type**  
University/education

**Website**  
<http://www.kcl.ac.uk/index.aspx>

**ROR**  
<https://ror.org/0220mzb33>

## **Funder(s)**

**Funder type**  
Government

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

## **Results and Publications**

### **Publication and dissemination plan**

Results will be communicated to participants, drug clinic staff and pharmacists through a summary of the results displayed in the drug clinic and presentations of results to staff and pharmacists. Results will be published in high-impact peer-reviewed academic journals. The protocol will be published in an academic journal.

**Intention to publish date**  
30/09/2024

### **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