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App-based financial incentives to encourage heroin abstinence in individuals with opioid use disorder

Submission date
28/11/2024

Recruitment status
No longer recruiting

Registration date
02/12/2024

Overall study status
Ongoing

Last Edited
15/04/2025

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
Opioid use disorder (OUD) is a serious public health problem and recovery is complex and difficult. Opioid-related deaths are rising globally, highlighting the urgent need for more effective treatment options. One promising approach is Contingency Management (CM), a psychological intervention where people are rewarded for positive changes, like attending clinical appointments and adhering to prescribed medications. This approach has been shown to also help people reduce their use of substances like alcohol, smoking, and illicit drugs. It has been effective for opioid use too, but the UK has been slow to adopt this approach, despite recommendations from health authorities. One way to make CM more accessible and reduce the burden on healthcare services is by delivering it remotely. Technology could automate key parts of CM, such as tracking progress and delivering rewards, which would make it easier for people to access and for healthcare providers to implement. Previous studies suggest that digital CM is effective, widely accepted by users and feasible. However, no fully digital CM programs currently exist for people using heroin. To address this gap, this study aims to explore whether it' s feasible and acceptable to deliver CM through mobile phones to encourage abstinence from heroin. The results could lead to a larger trial to test how well this approach works in helping people recover from opioid use disorder.

Who can participate?
Clients undergoing treatment for opioid use disorder and self-reporting continued heroin use might be eligible to participate

What does the study involve?
The research study involves assigning service users to one of two different groups. In one group, service users will receive financial incentives for heroin-negative samples. They will provide these results via a smartphone app three times a week. In the other group, service users will receive usual treatment only (opiate agonist treatment). Participants will be randomly assigned to their group by computer. Drug clinic staff and researchers cannot influence the selection. Participation lasts for 12 weeks. Participants will meet with the researcher and complete questionnaires every 4 weeks.

What are the possible benefits and risks of participating?
There are no immediate benefits from taking part, but participants will have a chance of receiving financial rewards for providing heroin-negative saliva tests. There are no risks.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
October 2023 to December 2026

Who is funding the study?
Society for the Study of Addiction (UK) as part of the PI's Academic Fellowship

Who is the main contact?
Dr Carol-Ann Getty, carol-ann.getty@kcl.ac.uk

Contact information

Type(s)

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Integrated Research Application System (IRAS)
343349

Central Portfolio Management System (CPMS)
65008

Study information

Scientific Title
Mobile telephone-delivered Contingency Management to reduce heroin use in individuals with opioid use disorder (CM4OUD)

Acronym

CM4OUD

Study objectives
This study aims to determine the feasibility of conducting a future randomised controlled trial of the clinical effectiveness of mobile telephone-delivered Contingency Management (mCM) to encourage heroin abstinence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/11/2024, West Midlands - South Birmingham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)2071048121, +44 (0)207 104 8019; southbirmingham.rec@hra.nhs.uk), ref: 24/WM/0216

Primary study design
Interventional

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Opioid use disorder

Interventions
The aim is to determine the acceptability and feasibility of conducting a future randomised controlled trial of the clinical effectiveness of mobile telephone-delivered Contingency Management (mCM) to encourage opioid abstinence.

The feasibility study will use a randomised controlled design, where 40 service users receiving treatment for OUD in UK addiction services will be recruited and randomly assigned (1:1) to receive treatment as usual or mobile-Contingency Management (mCM).

Participants assigned to the mCM arm will be provided with a smartphone containing the app. A testing schedule will be arranged for thrice weekly oral saliva testing. The research team will systematically review sleep schedules, work patterns and other routines with study participants, that could impose constraints on random testing. Schedules will be modified when necessary.

Participants will receive an app notification when an oral saliva test is due, and the result will be expected within 90 minutes of receiving the push notification. Participants will receive feedback upon submission. The research team will review submissions upon receipt for quality and validity (self-testing and results adequately displayed). Verified heroin-negative tests will result in notification of earnings.

Earnings will start at £2 for the first successful test result and escalate by £1 to reach a maximum value of £5 after four consecutive negative tests. A ‘reset’ procedure will be used, whereby a missed or positive sample will result in a return to £2 for the next negative test. Earnings will be automatically loaded to the app wallet. Participants can access and spend

vouchers from multiple vendors. Participants could earn a maximum of £174 over the 12-week study period.

There will be four forms of data collection:

1. Smartphone app
The smartphone app will automatically record data on participant usage and engagement, including the number of prompts responded to and test uploads. The accuracy and reliability of uploads will be measured automatically by the application. At the end of 12 weeks post-enrolment, these data will be extracted from the software system by a researcher and entered into an SPSS database. This will be stored with other trial databases in password-protected files on a King's College London (KCL) secure network drive. Usage of the mCM system will be captured through an automated system and any technical problems logged. App usability will be determined using the System Usability Survey.

2. Quantitative interviews
The researcher will conduct face-to-face interviews with participants at baseline (before enrolment) and at 12 weeks post-enrolment. These data will be collected for all participants unless the participant withdraws consent for continued collection of their data.

3. Qualitative interviews
Semi-structured qualitative interviews (analysed thematically) with participants receiving the intervention will assess acceptability and perceived benefits. Interviews will be conducted at the drug service following the completion of the mCM intervention. Interviews will be audio-recorded and guided by a topic list which is applied flexibly to ensure coverage of key themes while being sensitive to emergent themes.

4. Immunoassay tests
Immunoassays, which use antibodies to detect the presence of specific drugs or metabolites, are the most common method and allow for on-site instant detection of substances. Urine and saliva drug screening will be used to detect substance use. All tests will provide immediate results, and any used equipment will be discarded immediately after use. Urine samples will be collected from participants at baseline and weeks 4, 8 and 12 to determine the primary outcome measure. Samples will be collected in an all-in-one test kit and results displayed within several minutes. Samples will be disposed of afterwards. Oral fluid tests will be conducted remotely by participants twice weekly as part of the CM intervention to determine heroin use.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
The primary outcome of this feasibility trial is the number of eligible service users recruited over the 6-month recruitment period

Key secondary outcome(s)
Secondary feasibility outcomes include:
1. The number and percentage of screened service users eligible for inclusion and reasons for ineligibility recorded during the 6-month recruitment period

2. The number and percentage of eligible service users who consent to participate in the feasibility trial and the reasons for refusing consent recorded during the 6-month recruitment period
3. Adherence to the intervention based on app interactions, responses to push notifications, and uploads, recorded at recorded continuously during the 12-week intervention
4. The number/percentage attending follow-up interviews of those randomised, recorded at the end of the 12-week intervention
5. The number/percentage of oral saliva tests uploaded of sufficient quality, recorded continuously during the 12-week intervention
6. The number/percentage of urine samples conducted, collected at 4-weekly intervals following randomisation
7. Acceptability of the intervention among recipients exploring satisfaction and perceived benefits, assessed by qualitative interviews at the end of the 12-week intervention
8. Acceptability among treatment providers, exploring perceived appropriateness, intent for future adoption, and perceived positive or negative effects on service, assessed by qualitative interviews at the end of the 12-week intervention

The primary clinical outcome measure for a future confirmatory trial is the percentage of heroin-negative urine samples collected at 4-week intervals following randomisation

Secondary outcomes for the future confirmatory trial include:
1. Number/percentage retained in treatment over the 12-week intervention period
2. Drug use measured using the Opiate Treatment Index (Section 2 - Drug Use) at baseline, weeks 4, 8 and 12
3. Anxiety and depression states measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, weeks 4, 8 and 12
4. Social functioning measured using the Opiate Treatment Index at baseline, weeks 4, 8 and 12
5. Readiness to change measured using the Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES) at baseline, weeks 4, 8 and 12
6. Other substance use: opioid and non-opioid determined by urine immunoassays at baseline, weeks 4, 8 and 12

The researchers will also collect information needed to inform sample size calculations of the future confirmatory trial:
7. Appropriate summary statistics of the primary clinical outcome

The researchers will also collect information on:
8. Socio-demographic characteristics (including age, gender, ethnicity, employment status, living situation)

Completion date
14/12/2026

Eligibility

Key inclusion criteria
1. Receiving opioid agonist treatment (methadone or buprenorphine, including pro-longed release)
2. Self-reported heroin use at least 1 day/week
3. Aged >= 18 years
4. Able to operate an Android or iOS smartphone with acceptable capability

5. Willing to receive a 12-week CM intervention
6. Willing and able to provide informed consent

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Participating in any other research studies

Date of first enrolment
01/07/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Not provided at time of registration
United Kingdom
-

Sponsor information

Organisation
King's College London

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
Society for the Study of Addiction

Alternative Name(s)
The Society for the Study of Addiction, The Society for the Study of Addiction to Alcohol and other Drugs, The SSA, The Society for the Study and Cure of Inebriety, Society for the Study and Cure of Inebriety, Society for the Study of Addiction to Alcohol and other Drugs, SSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date