

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

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| Submission date 28/11/2024 | Recruitment status Recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 02/12/2024 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 15/04/2025 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |
| | | <input checked="" type="checkbox"/> 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)

Contact name

Dr Carol-Ann Getty

ORCID ID

<http://orcid.org/0000-0003-4151-7797>

Contact details

Addiction Sciences Building

4 Windsor Walk

London

United Kingdom

SE5 8AF

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carol-ann.getty@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

343349

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Randomized; Interventional; Design type: Treatment, 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

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/10/2023

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 40; UK Sample Size: 40

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

England

United Kingdom

Study participating centre

Not provided at time of registration

United Kingdom

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Sponsor information

Organisation

King's College London

Sponsor details

Strand

London

England

United Kingdom

WC2R 2LS

+44 (0)2078487306

vpri@kcl.ac.uk

Sponsor type

University/education

Website

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

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

Publication and dissemination plan

The results gathered will inform future developments of the smartphone app which will then be used in a larger research trial. Results will be presented at conferences, published in high-impact peer-reviewed journals and reported to the funders, the Society for the Study of Addiction (SSA) within 1 year of the trial ending.

Intention to publish date

14/12/2027

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