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Positive reinforcement targeting abstinence in substance misuse

Submission date
19/11/2012

Recruitment status
No longer recruiting

Registration date
19/11/2012

Overall study status
Completed

Last Edited
05/07/2021

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
Some people being receiving opioid substitution treatment (OST) with drugs like methadone, subutex, or suboxone either drop out of treatment early or continue to use heroin. Researchers in the USA have found that drug treatment clinics can help service users stay in treatment and reduce their heroin use by offering them shop vouchers. We call this positive reinforcement or contingency management (CM). Contingency Management has a strong evidence base in the US and has been recommended by National Institute for Health and Clinical Excellence (NICE) for UK implementation. However, the UK has little track record of applying contingency management in drug treatment. To find out if positive reinforcement might be helpful in reducing use of street heroin among opiate users receiving OST here in the UK, the aim of this study is to compare providing usual OST (methadone or subutex) to providing usual treatment with positive reinforcement.

Who can participate?
Heroin users, men and women, aged over 18 years, presenting to drug clinics for opiate treatment

What does the study involve?
The participating clinics are randomly allocated to one of three treatments: usual treatment (OST plus key work sessions), usual treatment plus positive reinforcement of attendance or usual treatment plus positive reinforcement of abstinence. Incentives are vouchers exchangeable for goods/services. After week 12, the contingency management is stopped and all participants receive only usual care. Urine samples are collected at various stages of the study. The practical problems encountered in recruiting sites, clinical staff and patients to this trial are examined.

What are the possible benefits and risks of participating?
There are no immediate benefits from taking part. Participants have a chance of receiving shop vouchers for attending interviews and key work sessions or providing urine samples negative for heroin. Participants involvement in the research could help improve the care provided at drug

treatment clinics. The information from this research could help improve opiate treatment programmes in the future. However, participants may be asked to attend more key work sessions and provide more urine samples than usual.

Where is the study run from?
Institute of Psychiatry, King's College London (UK)

When is the study starting and how long is it expected to run for?
November 2012 to April 2014

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
6113

Study information

Scientific Title
Cluster randomised controlled trial of two Contingency Management schedules targeting treatment attendance or abstinence from street heroin use in people treated for heroin dependence

Acronym

PRAISe

Study objectives
Contingency Management (CM) is a psychological intervention using positive reinforcement (usually in the form of praise and vouchers which can be exchangeable for goods) to encourage engagement with treatment and to promote behaviours congruent with treatment goals. This intervention is delivered as an adjunct to existing opiate substitute treatment.

The aim of this trial is to implement, observe and assess the acceptability, feasibility and clinical and cost effectiveness of Contingency Management (CM) strategies to improve treatment attendance and abstinence from heroin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South East Coast - Surrey, 25/07/2012, ref: 12/LO/0910

Study design
Multi-centre stratified cluster randomised trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental Health Research Network; Addictions

Interventions
Each of the 33 clinics will be their own cluster. Each clinic/cluster will be randomly assigned to one of the following trial arms (i.e., 20 participants per cluster, 11 clusters per arm, 220 participants in each arm and 660 in total):
1. TAU + 12 week schedule of weekly keywork appointments (no praise or voucher)
2. TAU + 12 week positive reinforcement (praise and voucher) for attending scheduled weekly keywork appointments
3. TAU + 12 week positive reinforcement (praise and voucher) for providing a weekly urine sample negative for opiates
Both CM schedules will offer the same valve of incentive over a 12 week period, but with different target behaviours (attendance vs abstinence). Incentives will be vouchers exchangeable at general supermarket chains.

Results are compared for the primary outcome at the 3rd month (weeks 9-12) in all three treatment conditions. The outcome of the trial will be determined by the mean number of urine tests results negative for opiates during weeks 9-12. After week 12, there will be complete cessation of rewards. In the follow-up phase (weeks 13-24) all participants will receive identical care with no CM. All primary and secondary outcomes at 12 weeks will be reassessed at 24 weeks for all participants. In addition, the number of opiate-negative urine test results during weeks 21-24 will be assessed.

The trial data will also be used to model differential costs of the two CM schedules vs current practice. A process evaluation will be conducted alongside the trial, in order to understand the implementation, delivery, fidelity and outcome of the trial intervention.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Mean number of opiate negative urine test results during weeks 9-12

Key secondary outcome(s))
1. Retention in treatment at the 3-month and 6-month follow-up
2. Urine test results at the 6-month follow-up (3 months post-CM)
3. Indices of physical, psychological and social well-being
4. Health economic and criminal justice outcomes

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Seeking new episode of OST treatment
3. Agree to 12 week treatment programme promoting abstinence
4. Regular users of street heroin in preceding month (self report 15/30 use and all UDS in past 4 weeks opiate positive)
5. Opiate dependent (meeting ICD-10 criteria) and at liberty to participate in the study for 24 weeks
6. Willing and able to provide informed consent
7. Male or female

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
552

Key exclusion criteria
1. Pregnant or breastfeeding
2. Active mental health problem
3. Patients referred into treatment under a criminal justice order
4. 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
19/11/2012

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College London
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
South London & Maudsley NHS Foundation Trust and Kings College London (UK)

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
NIHR Programme Grants for Applied Research ref: RP-PG-0707-10149 (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2021	05/07/2021	Yes	No
Protocol article	protocol	01/08/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes