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Telephone delivered Incentives (verbal praise and small financial incentives) for encouraging individuals receiving methadone treatment to attend their pharmacy to take their medication: testing the feasibility of undertaking a future trial

Submission date
15/03/2019

Recruitment status
No longer recruiting

Registration date
20/03/2019

Overall study status
Completed

Last Edited
08/01/2021

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Most people treated for heroin addiction are prescribed methadone which enables them to stop heroin use safely avoiding
withdrawal. People starting methadone take a daily dose under a pharmacist's supervision. Supervision prevents overdose. If a patient
misses their daily methadone they will experience opiate withdrawal and cravings which make them more likely to use heroin. If they miss
methadone for three days, people lose their tolerance to the drug and risk overdose. Unfortunately many patients do miss their doses. Research shows that small financial incentives can improve medication adherence. We have developed the technology to deliver such incentives using mobile phones but need to test the feasibility of this approach before conducting a full trial. The research aims to assess the feasibility of a trial to test whether attendance with supervised methadone consumption in pharmacies can be improved by using incentives delivered by mobile phone.

Who can participate?
Anyone over 18 years presenting to participating drug services for a new episode of opiate substitution treatment can take part.

What does the study involve?
We will survey pharmacists to find out about current methadone dispensing practice and develop the telephone incentive scheme to fit
routine practice. We will then look at the feasibility of conducting a trial to evaluate whether the intervention increases attendance at pharmacies. Three drug services (each with pharmacies

supervising 20 patients) will be recruited and randomly offered one of three approaches - which we plan to compare in the future trial. Some patients will receive telephone-delivered incentives (via text), others an appointment reminder (text), while others receive no texts. We will assess the acceptability of these approaches, how recruitment works and whether we can track patients to measure their outcomes.

What are the possible benefits and risks of participating?
There are no immediate benefits from taking part. You will have a chance of receiving small financial cash rewards for attending the pharmacy to take your methadone or receiving reminders. Involvement in the research may help improve the way you receive your medication. There are no risks of taking part. You will be asked to log your visits to the pharmacy onto the system via the tablet at the pharmacy counter. This might take a couple of minutes

Where is the study run from?
Lorraine Hewitt House, Brighton Terrace, Brixton, London

When is the study starting and how long is it expected to run for?
December 2018 to March 2019

Who is funding the study?
National Institute for Health Research

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

Patient & public involvement:
An existing service user advisory group will meet three times to advise on the delivery of telephone-delivered incentive scheme, patient information and dissemination.

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR PB-P9-0815-200053

Study information

Scientific Title
Telephone delivered Incentives for Encouraging adherence to Supervised methadone consumption: feasibility study for an RCT of clinical and cost effectiveness

Acronym
TIES

Study objectives
The aim is to assess the feasibility of conducting a future RCT of the clinical and cost effectiveness of telephone-delivered incentives, with the following objectives:
1. Assess the willingness of clusters (drug clinics and pharmacies) to be randomised
2. Assess numbers of eligible patients, rates of recruitment and suitability of recruitment procedures
3. Assess rates of follow-up at 12 weeks
4. Test accuracy of recording/logging in of attendance at pharmacy and drug clinics
5. Assess the acceptability of the study to patients
6. Identify different options for quantifying the primary outcome measure (adherence to medication) and assess the utility and practicality of these options
7. Characterise aspects of the primary outcome measure needed for a sample size calculation for a larger confirmatory trial (e.g. For a continuous outcome, mean and standard deviation, an initial estimate of the intraclass correlation to guide a sensible range for the cluster trial design effect)
8. Assess the most appropriate secondary outcome measures to determine patient benefit and cost-effectiveness, and the availability and usefulness of existing data sets including existing pharmacy dispensing data sets
9. Determine contextual factors and treatment processes that may impact on outcome (attendance).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 12/11/2018, South East London REC (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; 0207 104 8002; NRESCommittee.London-SouthEast@nhs.net), ref: 18/LO/1722

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Addiction

Interventions
At each site, two or three community pharmacies dispensing and supervising oral methadone to patients will be recruited. Three drug services will be randomised to deliver one of the following three interventions:
A. Supervised oral methadone + telephone delivered text messages providing positive reinforcement (via text messages) and small financial incentives (via trial debit card). Each time a participant attends their pharmacy and consumes their supervised oral methadone they will earn a financial reward of 50p. If they attend for six days consecutively they will earn a bonus reward of £5. The total possible financial reward is therefore £8/week or £96 over 12 weeks. If they attend they will receive a text message giving praise and a total of the money they have earned to date. Patients will be paid directly through debit card payment.
B. Supervised oral methadone + telephone delivered text messages providing reminders. Participants will be reminded via text message each day to attend their pharmacy for their supervised medication. Comparator group
C. Supervised oral methadone with no telephone text messages. Treatment as Usual.
Individuals seeking opiate substitution treatment at participating clinics will be approached by the assessment worker or keyworker and asked if they are willing to take part in the scheme. Patients are required to be receiving usual opiate substitution treatment involving 6 days a week supervised consumption of oral methadone . The scheme will be delivered for 12 weeks. The telephone text message intervention will be discontinued if participants move away from receiving oral methadone, supervised consumption or move to a non-participating pharmacy or drug clinic.

This feasibility study will use a cluster randomised controlled design where drug services and their allied community pharmacists are the cluster. Within each cluster, all participants will receive the same allocated condition.
A researcher will conduct face-to-face interviews with participants at baseline (before enrolment) and at 12 weeks post-enrolment. Second, the telephone software system will collect information from participants via tablet computers at each supervised methadone appointment over the 12-week period. This will include whether they attended and consumed their methadone or not. These data will be stored on a secure web site hosted by Mindwaves. Third, dispensing records kept by the allied pharmacies relating to trial participants will be provided to researchers after being pseudo-anonymised by the pharmacist.
Fourth, interviews and focus groups involving patients (including those who have discontinued

receiving the telephone system and those who have discontinued receiving oral methadone treatment), staff, and pharmacists will be recorded.

Intervention Type
Behavioural

Primary outcome(s)
Recruitment rate measured by number of patients recruited each week (of those entering opiate substitution treatment) over the 12-week recruitment period.

Key secondary outcome(s))
1. Feasibility outcomes
1.1 Rate of patients who are eligible and consent measured by percentage of screened patients who are eligible for inclusion in the feasibility trial and percentage of eligible patients who consent to participate. Data from Screening logs and Eligibility logs
1.2 Adherence to telephone text message system measured by percentage of matches between (a) daily pharmacy record and (b) record of attendance and medication compliance recorded on web-based telephone system. Data from daily pharmacy dispensing records and electronic database generated by software (this will record, due date, prescribed drug, doses and whether the patient missed their dose).
1.3 Percentage responding yes to 12 × weekly text message sent by researchers asking if they received all text message incentives or reminders for previous week (this will indicate whether they have mobile telephone and whether they are receiving text messages). Data from weekly text message received from participant
1.4 Accuracy of attendance measurement measured by percentage of matches between (a) daily pharmacy dispensing record and (b) record of attendance and medication compliance recorded in web-based software system. A ‘match’ is defined as agreement between (a) and (b) as to whether a participant attended their supervised methadone replacement appointment on a given day. Data from daily pharmacy dispensing records and electronic database generated by software (this will record, due date, prescribed drug, doses and whether the patient missed their dose.
1.5 Rates of follow-up measured by number and percentage of participants followed-up for research interview at 12 weeks post enrolment, by arm. Data from number of interviews conducted at 12 weeks post enrolment
1.6 The willingness of clusters (drug clinics and pharmacies) to be randomised measured by number and percentage of sites (drug services) enrolled relative to those approached measured by number and percentage of pharmacies enrolled relative to those approached. Data from recruitment log
1.7 Acceptability of the study to patients, drug clinic staff and pharmacists measured by qualitative views and experiences of patients, drug clinic staff and pharmacist. Data from focus groups and interviews with all participants, drug clinic staff and pharmacists at 12 weeks post enrolment
1.8 Contextual factors and treatment processes that may impact on outcome measured by qualitative views and experiences of patients, drug clinic staff and pharmacist. Data from focus groups and interviews with all participants, drug clinic staff and pharmacists at 12 weeks post enrolment
2. Primary outcomes for exploration for a future confirmatory trial
2.1 Adherence to medication measured by 1) percentage of days (during 12 weeks post enrolment) when medication was taken; 2) Median number of days (during 12 weeks post enrolment) when medication was not taken; 3)Likert-like scale categorising participants according to different missed dose patterns (during 12 weeks post enrolment) – percentage in

each category; and 4) Number of days to missed doses outcome analysed using repeated events survival analysis. Data from daily pharmacy dispensing data sets will be authoritative data source on adherence to medication. Medication compliance recorded on software system, including patient ID, date and time, whether they attended or did not attend will be compared with pharmacy dispensing to check accuracy.
2.2 Aspects of the primary outcome measure needed for a sample size calculation for a future confirmatory trial measured by 1) Appropriate summary statistics, for example, for continuous outcomes, mean and standard deviation; 2) Estimate of the intraclass correlation for the clusters and 3) Qualitative availability and usefulness of existing pharmacy dispensing data sets. Data from pharmacy dispensing data sets and Medication compliance recorded on software system, as above.
3. Secondary outcomes of a future confirmatory trial
3.1 Retention in treatment measured by number and percentage retained in treatment over the 12-week intervention period. Data from research interview undertaken with all participants at baseline (pre-enrolment) and at 12 weeks post enrolment
3.2 Illicit drug use measured by Opiate Treatment Index (Section 2 –Drug Use) (Validated) including: Number and percentage using illicit street drugs in past 30 days; Median number of days used illicit street drugs in past 30 days; Median number of days injected illicit street drugs use in past month; Route of use (number/percentage for each);Average cost of each drug used on average day. Data from research interview undertaken with all participants at baseline (pre enrolment) and at 12 weeks post enrolment.
3. 3. Other (health and social status) measured by
3.3.1 Alcohol Use Disorders Identification Test (AUDIT) (Validated, mean total score)
3.3.2 Hospital Anxiety and Depression Scale (HADS) (Validated, mean total anxiety and depression subscale scores); Social functioning measured using the Opiate Treatment Index (Validated, mean social functioning subscale score);
3.3.3 Physical and mental health status (Short form -36) subscale mean scores);
Data from research interview undertaken with all participants at baseline (pre enrolment) and at 12 weeks post enrolment
3.4. Socio-demographic characteristics measured by: Mean and SD of age; Number and percentage in each gender group; Number and percentage in each ethnicity group; Number and percentage in each employment status group; Number and percentage in each living situation group. Data from Research interview; undertaken with all participants at baseline (pre enrolment)
4. Outcomes for economic evaluation: Economic data collection measured by:
4.1 Resource use schedules AD-SUS (with questions about crime committed removed)
4.2 EQ -5D-5L measure of health-related-quality of life (Validated, mean utility and VAS scores and incorporated in health economic analysis)
4.3 ICECAP-A (i. Completion rates and ii. Missing data (item missing and questionnaire missing), plausible values and inconsistencies. Data from research at baseline (pre-enrolment) and at 12 weeks post enrolment.
5. Process outcomes
5.1. Determine contextual factors that impact on acceptability of intervention (including take-up and compliance) and trial procedures to both clinic and pharmacy staff and participants measured by focus groups with all participants and interviews with participating drug service staff and pharmacists at 10 weeks post enrolment.

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Aged > 18 years
2. Presenting to participating drug services for a new episode of opiate substitution treatment (OST) (patients must not have been receiving a prescription for methadone or other opiate substitution medication for >4 weeks and excludes those who have been transferred in from another service or prison)
3. Prescribed oral methadone
4. Receiving their supervised oral methadone at the local community pharmacy six days a week
5. Receiving supervised consumption of oral methadone from participating pharmacies
6. Owns a mobile phone
7. Willing and able to provide informed consent. Therefore, they must be able to read English and not require the service of an interpreter.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
11

Key exclusion criteria
1. Cannot read English AND would require the service of an interpreter to understand a brief oral description of the study
2. Already entered the trial.
3. Previously attended the service (drug clinic) and were discharged within the last three weeks

Date of first enrolment
17/12/2018

Date of final enrolment
24/03/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lorraine Hewitt House
Brighton Terrace
Brixton
London
United Kingdom
SW9 8DG

Sponsor information

Organisation
Kings College London & South London & Maudsley NHS Foundation Trust

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to this being a feasibility study.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/01/2021	08/01/2021	Yes	No
Protocol article	protocol	10/12/2019	26/10/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes