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Financial incentives to improve adherence to anti-psychotic medication

Submission date	Recruitment status	[X] Prospectively registered
02/04/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/04/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/09/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 07/60/43

Study information

Scientific Title
Financial incentives to improve adherence to anti-psychotic maintenance medication in non-adherent patients: a cluster randomised controlled trial

Acronym
MfM

Study objectives
The objective of the study is to establish the effectiveness and cost-effectiveness of using financial incentives to improve adherence to anti-psychotic maintenance medication in patients with poor adherence with whom all conventional methods to achieve adherence have failed.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/076043
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0017/51902/PRO-07-60-43.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised 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
Severe mental illness (psychosis)

Interventions
Patients in the assertive outreach teams that have been allocated to the intervention will be offered a financial incentive for each depot injection of anti-psychotic medication they receive, for a 12-month period. Patients will receive £15 for one injection with the total sum not exceeding £60 for a four-week period (the maximum number of injections is 4 per month).

The control group will receive treatment as usual.
The total duration of the intervention will be 12 months with a 6-month follow-up period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Adherence to anti-psychotic maintenance medication during the 12-month trial period. Adherence will be measured, objectively, as the percentage of prescribed depot injections actually taken. As the primary outcome, the percentage will be used as a continuous variable. However, we will also analyse the percentage in a dichotomised way, comparing the ratio of patients with 'good' adherence (i.e., greater than or equal to 80% of prescribed depots taken) in the two conditions.

Secondary outcome measures
1. The time 'slippage' of taking depots, defined as the percentage of the prescribed time interval that has expired before the depot is taken
2. Clinical improvement as assessed on the Clinical Global Impression Scale (CGI) by the treating consultant psychiatrist at the end of the 12-month period
3. Number of involuntary and voluntary hospital admissions during the trial period
4. Costs of care: data on the use and frequency of use of inpatient care, outpatient care (including home visits, home treatment), and other health services during the 12-month treatment period will be obtained from case notes and electronic administrative data bases. Costs for the intervention will be estimated for each participating team from information provided by staff. Established national unit costs will be used to estimate direct health care.
5. The number of attempted and completed suicides, incidences of physical violence, police arrests and days spent at work/training/education will also be recorded over the 12-month trial period
6. Subjective quality of life and satisfaction with medication which will be assessed at the beginning and end of the intervention period using the 11-item scale established in the DIALOG trial. The scale contains 11 items asking patients to rate their satisfaction with eight life domains and three treatment aspects, one of which is medication, on a scale ranging from 1 (lowest satisfaction) to 7 (highest satisfaction).
7. Continuation with MfM (in intervention group only) and adherence during a 6-month follow up period will be taken from the medical records
8. Teams in the intervention group will be asked after 6 months, 12 months and 18 months about all aspects of experiences with the scheme including whether patients on MfM asked for an increase of the incentive, and whether other patients with hitherto good adherence also asked for financial incentives and/or became poorly adherent in order to be eligible for MfM. This will be done using open questions with a written documentation of the answers.

Overall study start date
01/09/2009

Completion date
30/11/2012

Eligibility

Key inclusion criteria
The only inclusion criterion for teams is that they are a dedicated assertive outreach team (AOT) and operate a corresponding policy. The only exclusion criteria are lack of willingness to participate and an already existing practice of money for medication (MfM).

For patients in the AOTs there are the following inclusion criteria:
1. Being cared in the AOT for at least 4 months
2. Aged between 18 and 65 years of age, either sex
3. Capacity to give informed consent to participate in the study and actual written informed consent
4. An established diagnosis of schizophrenia, schizo-affective psychosis, or bipolar illness according to the International Classification of Diseases, 10th Edition (ICD-10)
5. Being prescribed depot injections of anti-psychotic medication
6. Poor adherence to anti-psychotic medication, i.e., missed 50% or more of prescribed depot injections, over the last 4 months (so that the percentage of taken depots is based on a minimum of 4 prescribed depots)
7. Failure of all other methods available to the team to ensure adherence to medication

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
136 patients from 34 assertive outreach teams

Key exclusion criteria
1. Learning difficulty
2. Poor command of English so that clinical communication and discussion of agreements is impaired

Date of first enrolment
01/09/2009

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newham Centre for Mental Health
London
United Kingdom
E13 8SP

Sponsor information

Organisation
Barts and The London Queen Mary's School of Medicine and Dentistry (UK)

Sponsor details
c/o Gerry Leonard
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Sponsor type
University/education

Website
http://www.smd.qmul.ac.uk/

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	28/09/2009		Yes	No
Results article	results	07/10/2013		Yes	No
Results article	results	01/04/2015		Yes	No
Results article	results	01/08/2015		Yes	No
Results article	results	08/10/2015		Yes	No
Results article	results	01/09/2016		Yes	No
Results article	results	21/09/2016		Yes	No