ISRCTN33576045 https://doi.org/10.1186/ISRCTN33576045

Contingency intervention for reduction of cannabis in early psychosis

Submission date
20/10/2011

Recruitment status
No longer recruiting

Registration date
28/11/2011

Overall study status
Completed

Last Edited
29/08/2019

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
Cannabis use increases the problems that people with severe mental health problems face. For example, young people with psychosis who use cannabis are more likely than those who do not to have difficulty recovering from their initial symptoms of psychosis, to relapse once they have recovered, to commit crimes, and less likely to work. Their need to rely on welfare benefits and frequent use of expensive services such as hospital has implications for society as a whole. Early intervention services (EISs) are a type of mental health team now available throughout England, They aim to improve prognosis for young people with early psychosis, reducing the likelihood that they will relapse and helping them achieve their goals, which may include getting back to work or education. Almost half the young people on EIS caseloads use cannabis, so that it is an important obstacle to recovery. Many young people who have developed a psychotic illness have some motivation for reducing their cannabis use. However, we do not have a really effective treatment available for helping them to do so. It has proved difficult to design treatments that work for drug use among people who have psychotic illnesses. Our aim is to try out a new approach called Contingency Management that is increasingly used in drug services but has not been studied a lot among people with psychosis.

Who can participate?
The participants in our study will be people aged between 18 and 39 who are currently under the care of an early intervention service for psychosis, and who have used cannabis in the past 6 months. They will be men and women.

What does the study involve?
The study will compare two approaches to helping people reduce their cannabis use. Group A will receive both a new approach called Contingency Management and a short educational package. Contingency Management involves receiving voucher rewards, to be spent in local shops, on condition of attending appointments and providing urine samples free from cannabis. Rewards increase with increasing weeks of abstinence over a 3 month period. The educational package is intended to help people to decide whether or not they wish to carry on using cannabis. Group B will receive the educational package only.

We will then compare Group A and Group B, assessing over an 18 month period which group is more likely to relapse, to use cannabis, to have more severe symptoms of psychosis, and to be in work or education.

What are the possible benefits and risks of participating?
The main benefit to participants will be if the study treatments, especially that received by Group A, turns out to help people to reduce their cannabis use. This may have significant benefits for their health and progress towards their goals in life. The participants in Group A will also benefit from receiving voucher rewards if they can avoid using cannabis. There are few significant risks: the vouchers will not be exchangeable for alcohol, but it is possible that some participants may find ways of informally trading them for money to purchase substances.

Where is the study run from?
The lead centre is the Mental Health Sciences Unit at University College London. There will be n initial study in three London Boroughs Camden, Islington and Hackney and in Coventry and Warwickshire NHS Foundation Trust, linked to the University of Warwick. If this goes well, we will add further teams to a full-scale study, based around UCL, the University of Warwick, the University of East Anglia and Kings College London.

When is the study starting and how long is it expected to run for?
We expect the study to start in January 2012. Over the first 18 months, we will carry out an initial study to test whether we can recruit participants and whether the study treatments are acceptable to patients and staff. If it goes well, more centres will be added to make it a full study. The total study period will be four and a half years, ending in July 2016.

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme

Who is the main contact?
Prof. Sonia Johnson
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 09/144/50

Study information

Scientific Title
Randomised controlled trial of the clinical and cost-effectiveness of a contingency management intervention for reduction of cannabis use and of relapse in early psychosis

Acronym
CIRCLe

Study objectives
Time to relapse will be significantly greater in a group of early intervention service users who receive psychoeducation combined with contingency management (voucher rewards for evidence of abstinence) than in a group who receive the psychoeducation only.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0914450
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/55170/PRO-09-144-50.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Feasibility pilot individually randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Psychotic illnesses including schizophrenia, schizo-affective disorder and bipolar disorder with psychotic symptoms

Interventions
Experimental group: Contingency management involving voucher rewards for abstinence demonstrated by urinalysis together with psychoeducation delivered by care coordinators.

Control group: Psychoeducation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Time to relapse is assessed as admission to acute mental health care over 18 months

Secondary outcome measures
1. Presence of cannabis on urinalysis at 3 months and at 18 months of follow up
2. Positive symptom severity measured by Positive and Negative Syndrome Scale (PANSS) at 3 months and 18 months
3. Engagement in work or study is assessed by participant self report at 3 months and 18 months

Overall study start date
01/09/2010

Completion date
31/10/2017

Eligibility

Key inclusion criteria
1. Under the care of an early intervention service for psychosis
2. Diagnostic criteria for EIS entry require a first psychotic episode significantly impairing functioning and lasting more than a week
3. Problematic cannabis use is operationalised as having used cannabis at least once in at least 12 of the previous 24 weeks
4. Aged 18-39, male and female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
39 Years

Sex
Both

Target number of participants
544 including 68 participants in feasibility pilot study

Total final enrolment
551

Key exclusion criteria
Insufficient English to complete the study assessments

Date of first enrolment
01/06/2012

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
W1W 7EY

Sponsor information

Organisation
University College London (UK)

Sponsor details
c/o Dr Nick McNally
Director of Research Support

Joint University College London Hospitals/ University College London/ Royal Free Hospital Biomedical Research Unit
25 Grafton Way
London
England
United Kingdom
WC1E 6DB

Sponsor type
University/education

Website
http://www.ucl.ac.uk/joint-rd-unit/

ROR
https://ror.org/02jx3x895

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
Planned publication of study results in a peer reviewed journal. Submission of a report to funders in November 2017.

Intention to publish date
01/05/2018

Individual participant data (IPD) sharing plan

The current 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/10/2016		Yes	No
Participant information sheet	version V4	12/05/2014	05/01/2017	No	Yes
Results article	results	15/08/2019	16/08/2019	Yes	No
Other publications	report	01/08/2019	29/08/2019	Yes	No