ISRCTN88275061 https://doi.org/10.1186/ISRCTN88275061

HELPER Programme (Substance Misuse) - A phase-specific psychological therapy for people with problematic cannabis use following a first episode of psychosis (ReCAP)

Submission date
23/08/2012

Recruitment status
No longer recruiting

Registration date
23/08/2012

Overall study status
Completed

Last Edited
11/05/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Schizophrenia and related psychoses often make it harder for sufferers to concentrate, remember things like appointments, change the way they think about things when they need to (flexibility) and do several things at the same time. This might also make it harder for people to take part in talking therapies like Cognitive-behavioural therapy (CBT). The researchers running this study hope to use Cognitive Remediation (CR) to help people get more out of CBT. CR is a way of training the brain to deal with difficulty in concentration, memory and so on, based on practicing puzzles and other tasks. Other studies have shown it can work to improve these things but have not used it before CBT. This study will investigate whetherthe use of a course of Cognitive Remediation (CR) prior to participation in CBT will improve the effectiveness of the CBT. CR is a form of brain-training using a programme of mental puzzles and other tasks which is known to be effective in improving cognitive capacities.

Who can participate?
Patients aged between 16-35 with a mental health disorder that take cannabis.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given 40 hours of CR over a 12 week period before CBT. Those in group 2 are given 40 hours of social support over a 12 week period before CBT. All participants are given CBT for a period of between 12 and 30 weeks. Each participant is assessed at the start of the study using a wide range of measures including the severity of their symptoms and their cognitive capacities (how well they think). They are assessed again after they have completed CR or social support and every 6 weeks for another 30 weeks after they start their CBT.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Lancashire Care NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2009 to April 2011

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

Who is the main contact?
Ms Louise Worrell
louise.worrell@lancashirecare.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Ms Louise Worrell

Contact details
Lancashire Care NHS Trust
Sceptre Way
Bamber Bridge
Preston
United Kingdom
PR5 6AW
-
louise.worrell@lancashirecare.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4756

Study information

Scientific Title
HELPER Programme (Substance Misuse) - A phase-specific psychological therapy for people with problematic cannabis use following a first episode of psychosis (ReCAP)

Acronym
HELPER (ReCAP)

Study objectives
We are conducting an exploratory trial to evaluate whether a psychological therapy following a first episode of psychosis is effective at reducing cannabis use when compared to usual care. This study will also investigate whether a brief intervention (4.5 months) is as effective as a longer one (9 months). This is a randomised controlled trial with 3 treatment groups, long-term treatment, short-term treatment, and treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
08/H1015/82

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
64 patients waiting for CBT after their first episode of schizophrenia, who agree to take part, will be randomly selected either for CR or support from a Support Time and Recovery Worker. They will see either the therapist for 40 hrs or the support worker for the same amount of time over 3 months. After this both group will have CBT as part of normal NHS service, for 12 - 30 sessions. Participant's symptoms and neuropsychological skills will be assessed at recruitment and after 12 weeks by an assessor is blind to which group they are in. They will then have delusions and hallucinations reassessed for every 6 weeks for another 30 weeks, during CBT.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Cannabis

Secondary outcome measures
No secondary outcome measures

Overall study start date
05/01/2009

Completion date
20/04/2011

Eligibility

Key inclusion criteria
1. Meeting DSMIV criteria for schizophrenia, schizophreniform disorder, schizoaffective disorder, delusional disorder, or psychosis not otherwise specified using a checklist of criteria and review of case notes; and confirmation of this diagnosis using the structured clinical interview for DSMIV Axis 1 disorders
2. DSMIV diagnosis of cannabis dependance or abuse using the appropriate sections of the structured clinical interview
3. A history of cannabis use of at least 1 day per week in at least half the weeks in the 3mths prior to assessment (those who are misusing other illict substances or alcohol will not be excluded)
4. Aged 16-35
5. No significant history of organic factors implicated in the aetiology of psychotic symptoms
6. Male & female participants

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 135

Key exclusion criteria
1. No stable accommodation (i.e. street homeless or roofless)
2. Does not possess sufficient English to reliably complete assessments
3. Not able to give informed consent

Date of first enrolment
05/01/2009

Date of final enrolment
20/04/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lancashire Care NHS Trust
Preston
United Kingdom
PR5 6AW

Sponsor information

Organisation
Lancashire Care NHS Trust (UK)

Sponsor details
Sceptre Point
Sceptre Way
Walton Summit
Preston
England
United Kingdom
PR5 6AW

Sponsor type
Hospital/treatment centre

Website
http://www.lancashirecare.nhs.uk

ROR
https://ror.org/03zefc030

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

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?
Results article	results	01/10/2014		Yes	No
Results article	results	01/03/2015		Yes	No
Interim results article	interim results	01/04/2015		Yes	No