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

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------|--|-----------------------------|--|--|
| 23/08/2012 | | ∐ Protocol | | |
| Registration date | Overall study status | Statistical analysis plan | | |
| 23/08/2012 | Completed | [X] Results | | |
| Last Edited | Condition category Mental and Behavioural Disorders | 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
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Contact information

Type(s)

Scientific

Contact name

Ms Louise Worrell

Contact details

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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 |