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HELPER Programme - cognitive remediation in first episodes of schizophrenia

Submission date	Recruitment status	[ ] Prospectively registered
05/09/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/11/2012	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/12/2017	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Schizophrenia and other related mental health problems 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). We 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 assess whether the use of a course of CR before CBT will enhance the effectiveness of the CBT.

Who can participate?
Patients aged 18 - 35 years diagnosed with schizophrenia or a related mental health problem, on a waiting list for CBT.

What does the study involve?
Participants are randomly allocated to receive either 40 hours of CR or 40 hours of social support delivered over 12 weeks. Participants then proceed to CBT for between 12 and 30 weeks. Participants' symptoms are assessed at the start of the study and when participants have completed CR or social support. During the course of CBT participants will be re-assessed every 6 weeks and at 30 weeks after the start of 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 study starting and how long is it expected to run for?
January 2009 to July 2010.

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

Who is the main contact?
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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
4755

Study information

Scientific Title
HELPER Programme (Cognitive Remediation) - a randomised controlled trial of cognitive remediation in first episodes of schizophrenia

Study objectives
Many people with Schizophrenia have difficulties with neuropsychological skills (like attention, planning, memory, design and perception). Cognitive Remediation (CR) is a method for improving them, in essence a form of 'brain training', consisting of regular practice on a number of mental puzzles. In clinical trials CR has improved several neuropsychological difficulties, insight into those difficulties, and even delusions and hallucinations. It often works when linked to other forms of rehab or psychological treatment. Cognitive Behavioural Therapy (CBT) is used in addition to medication as a treatment for schizophrenia symptoms but depends on

participants having the kind of neuropsychological skills targeted by CR (e.g. attention, memory etc).

The study aims to see whether 3 months of computer-based CR, while on the waiting list for CBT, will improve CBT's results following a first episode of psychosis.

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 40hrs or the support worker for the same amount of time over 3mths. 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.

More details can be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=4755

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bolton Research Ethics Committee, 23/12/2008, ref: 08/H1009/76

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
Schizophrenia, Psychosis

Interventions
Consenting patients waiting for CBT for psychosis after their first episode of schizophrenia are randomly allocated to either cognitive remediation (CR) or a time-matched social support comparison group by an independent administrator. The CR group engage in computer based cognitive remediation (with the CIRCUITS virtual reality based CR programme) for a total of 40 hours over 3 months. A CR therapist also supports them face-to-face for at least 1h per week.

The social support comparator group are exposed to a support time and recovery worker for a matched period. After this both groups have routine CBT for 12 - 30 sessions delivered by specifically trained, accredited, supervised CBT for psychosis therapists as part of NHS Early Intervention Services.

Participants' symptoms and neuropsychological skills are assessed at recruitment and after 12 and 42 weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
PSYRATS, a measure of delusions and hallucinations. PSYRATS is reassessed every 6 weeks during the 30week CBT envelope (weeks 12-42). A final PSYRATS is completed at 54 weeks.

Secondary outcome measures
1. PANSS
2. Calgary Depression
3. Insight Scale and IPQ attitude scores
4. Time to relapse and readmission

Overall study start date
19/01/2009

Completion date
31/07/2010

Eligibility

Key inclusion criteria
1. Participants which they have suffered a 1st episode of psychosis that meets DSM IV criteria for schizophreniform disorder, schizophrenia, schizo-affective disorder, delusional disorder, or psychosis Not Otherwised Specified (NOS)
2. Aged 18 - 35 years
3. Receiving standard care from Early Intervention Service
4. Male and female participants

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit

35 Years

Sex
Both

Target number of participants
UK Sample Size: 64

Key exclusion criteria
DSM IV criteria for substance misuse or organic brain disease

Date of first enrolment
19/01/2009

Date of final enrolment
31/07/2010

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	01/07/2014		Yes	No