

# HELPER Programme - cognitive remediation in first episodes of schizophrenia

<b>Submission date</b> 05/09/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/12/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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?  
Louise Worrell  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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.

**Key secondary outcome(s)**

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

**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 Otherwise Specified (NOS)
2. Aged 18 - 35 years
3. Receiving standard care from Early Intervention Service
4. Male and female participants

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

35 years

**Sex**

All

**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

United Kingdom

England

## Study participating centre

Lancashire Care NHS Trust

Preston

United Kingdom

PR5 6AW

# Sponsor information

## Organisation

Lancashire Care NHS Trust (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

## 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?
<a href="#">Results article</a>	results	01/07/2014		Yes	No