ISRCTN55488371 https://doi.org/10.1186/ISRCTN55488371

Computerised Cognitive Remediation Therapy for Schizophrenia

Submission date
29/04/2010

Recruitment status
No longer recruiting

Registration date
29/04/2010

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People who have received a diagnosis of schizophrenia frequently have problems with thinking skills such as memory and concentration. These difficulties can make it difficult to take part in everyday activities such as socialising or working, which are important for a good quality of life. Cognitive remediation (CR) is a psychological therapy which can help people improve their thinking skills and this seems often to have a positive effect on activities in daily life. CR is beginning to be offered by health services, and researchers are trying to understand how it works. A state-of-the-art new computerised CR programme called CIRCuiTS has been developed. It works by teaching people to use strategies and to understand and manage their thinking skills better, first using computerised games and puzzles, but then in daily life activities such as in work, socialising or using public transport. The aim of this study is to test whether CIRCuiTS is user-friendly enough to allow therapists to deliver therapy sessions easily and for people with a schizophrenia diagnosis to carry out sessions independently at home and to investigate whether CIRCuiTS is effective in helping people to improve their thinking skills and performance in daily life.

Who can participate?
Adults aged 18-65 years who have a received a diagnosis of schizophrenia.

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives their normal mental health treatment. The other group received CIRCuiTS at least three times a week for up to 12 weeks, in addition to their normal mental health treatment. The CIRCuiTS sessions are carried out with the support of a psychological therapist, but participants are also encouraged to carry out additional sessions alone at home. CIRCuiTs involves learning to use strategies to help improve performance on computerised thinking skills tasks, and then afterwards, to use the same strategies in daily life.
Before and after the therapy (or after three months for those who receive only their normal mental health treatment), and then again three months later, participants are asked to complete a number of thinking skills puzzles and questionnaires so that we can test if CIRCuiTS is more helpful than participants' usual treatment.

What are the possible benefits and risks of participating?
Participants may benefit from improvement in their symptoms. There are no notable risks with participating, however participants may find the programme stressful.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
May 2010 to November 2012.

Who is funding the study?
NIHR (UK)

Who is the main contact?
Professor Til Wykes
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5661

Study information

Scientific Title

An exploratory two-group randomised controlled trial of computerised cognitive remediation therapy (CRT) and treatment as usual versus treatment as usual alone in schizophrenia patients

Acronym
CIRCUITS-3

Study objectives
Cognitive difficulties are a limiting factor on the functional and quality of life outcomes for people with schizophrenia. Cognitive remediation therapy (CRT) is a psychological therapy shown to improve these thinking skills. Currently therapy involves a considerable amount of therapist time but a new development, computerised CRT (CIRCuiTS), may reduce the need for direct individual face to face therapy so that more people can access it. However, the efficacy of this form of therapy has yet to be determined.

This trial is an exploratory two-group randomised controlled trial (RCT): CIRCuiTS and treatment as usual (TAU) compared to TAU. Outcomes are measured at weeks 0, 12, 26. Participants are independently randomised and raters blind to group allocation. Primary outcomes are measured in three cognitive domains: long-term memory, working memory and executive function. Secondary outcomes include social functioning, service use and self-esteem.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Joint South London and Maudsley and the Institute of Psychiatry NHS Research Ethics Committees, 01/07/2008, ref: 08/H0807/26

Study design
Randomised interventional treatment 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 in the interventions section below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Schizophrenia; Disease: Schizophrenia

Interventions

Current interventions as of 03/05/2017:
A two arm single blind randomised superiority trial comparing a new generation computerised cognitive remediation programme (CIRCuiTS) plus treatment-as-usual (TAU) with TAU alone in 93 people with a diagnosis of schizophrenia. Cognitive, social functioning and symptom outcomes were measured at week 0 pre-randomisation (baseline), week 12 (post-treatment) and week 26 (follow-up).

CIRCuiTS is a web-based computerised CR therapy, delivered by a therapist but supplemented with independent sessions to facilitate massed practice. It targets metacognition, particularly strategy use, in addition to providing massed practice of basic cognitive functions. The therapist facilitates motivation, metacognitive and strategy development and generalisation of learning by encouraging the participant to learn about and regulate their cognitive performance and to transfer this learning to meet real-world goals. Therapists provide additional scaffolding for CR tasks to ensure consistent successful performance. Independent sessions involve carrying out cognitive tasks allocated by the therapist to ensure scaffolded learning.

Real-world cognitive goals are set collaboratively, and then CIRCuiTS tasks are used to identify cognitive strengths and difficulties and factors affecting cognitive performance. The primary cognitive targets are attention, memory and executive functioning and repetitive tasks gradually increase in difficulty in line with individual highly successful performance. Participants develop a set of personalised strategies to improve their cognitive performance, and achieve their goals.

The CR tasks are either ‘abstract’ (neutral content, such as numbers, and designed to target specific cognitive functions) or ‘exercises’ (cognitively complex and ecologically valid) associated with work, social situations, cooking, shopping and travelling. Therapists encourage participants to apply the skills learnt to daily life and to practice in vivo.

CIRCuiTS is offered at least three times a week (maximum 12 weeks), up to 40 sessions lasting up to an hour. Where possible, according to participants’ ability and choice, therapists encouraged them to carry out additional independent sessions.

Previous interventions:
CIRCuiTS is a new computerised cognitive remediation package for schizophrenia that aims to improve attention, memory and cognitive flexibility. CIRCuiTS is an eLearning platform that guides participants through a series of mental exercises with the goal of strategy formation. This approach is known to facilitate generalisation to everyday function. There are 40 sessions of therapy taking place up to 5 times a week.

Follow-up length: 3 months
Study entry: single randomisation only

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Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 03/05/2017:
1. Verbal working memory is assessed using Digit Span a working memory task at baseline, 12 weeks, and 26 weeks
2. Visual memory is assessed using the Rey Osterreith Complex Figure, a visual memory test at baseline, 12 weeks, and 26 weeks
3. Verbal executive function is assessed using the Hayling Sentence Completion test, measuring response inhibition at baseline, 12 weeks, and 26 weeks
4. Visual executive function was assessed using the Wisconsin Card Sorting Test, testing abstraction and cognitive flexibility at baseline, 12 weeks, and 26 weeks

Previous primary outcome measures:
Cognitive test battery, measured at timepoint 1 (0 weeks), 2 (12 weeks) and 3 (26 weeks)

Secondary outcome measures
Current secondary outcome measures as of 03/05/2017:
1. Community functioning is assessed using the Time Use Survey (a semi-structured interview recording participants' time use, selected to capture widely disparate clinically meaningful increases in functional activity at baseline, 12 weeks, and 26 weeks
2. Symptoms are assessed using the Positive and Negative Syndrome Scale at baseline, 12 weeks, and 26 weeks

Previous secondary outcome measures:
1. Community functioning, measured at timepoint 1, 2 and 3
2. Psychiatric symptoms, measured at timepoint 1, 2 and 3

Overall study start date
02/11/2009

Completion date
02/11/2016

Eligibility

Key inclusion criteria
Participants will be entered into the study if they have:
1. A diagnosis of schizophrenia
2. Have been in touch with the mental health services for at least one year
3. Aged between 17 and 65 years old, either sex
4. Have a known cognitive deficit (poor performance in memory [digit span] and/or cognitive flexibility [WCST or Hayling Sentence Completion Test] in addition to poor social functioning [score of 2 or more on Social Behaviour Schedule])

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
1. Plan to change their medication during the therapy phase of the study
2. Known substance dependence
3. Evidence of an organic cause to their cognitive difficulties (e.g. history of head injury)

Date of first enrolment
24/05/2010

Date of final enrolment
29/05/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
South London and Maudsley NHS Trust (UK)

Sponsor details
Clinical Treatment Centre
1st Floor, Maudsley Hospital
Denmark Hill
London

England
United Kingdom
SE5 8AZ

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme

Results and Publications

Publication and dissemination plan
Planned publication in Psychological Medicine.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from til.wykes@kcl.ac.uk

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	04/09/2017	24/01/2019	Yes	No