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ECLIPSE Study 9: Building resilience and recovery through enhancing cognition and quality

Submission date
06/06/2016

Recruitment status
No longer recruiting

Registration date
06/06/2016

Overall study status
Completed

Last Edited
08/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Non-affective psychosis is the name given to a group of mental health conditions in which a person suffers from psychosis that is not related to mood. Schizophrenia and delusional disorders are examples of non-affective psychoses. These disorders involve a wide range of symptoms, including seeing or hearing things that are not there (hallucinations), having beliefs that do not reflect reality (delusions) and distinct changes in personality or behaviour. These symptoms can be very difficult for patients to deal with, often affecting the way they live their lives and their ability to work. The extent of cognitive problems (problems with thought, learning and/or memory) in people with these conditions is a good predictor functional recovery (how well someone can function in life), even with the best possible rehabilitation opportunities and medication. A new psychological treatment known as cognitive remediation (CRT) can improve both cognitive and functional recovery, including social relationships, work and studying. The ideal time to provide CRT is when a patient is being seen by the Early Intervention Services (for young people experiencing psychosis for the first time, and during the first three years following this first episode) as it is well known that it is more effective for younger people and may have larger effects on functioning if the intervention happens at the earliest opportunity. The aim of this study is to investigate the best way of putting into effect CRT for people in Early Intervention Services by assessing the degree that participants are able to achieve their personal goals.

Who can participate?
Adults aged between 16 and 45 who have a non-affective psychosis and have been attending an Early Intervention Service for at least three months or any individual within 5 years of their first episode of psychosis.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in intensive CRT. This involves receiving twice weekly individual therapy sessions for ten and a half weeks. Each session lasts for 60-180 minutes and involves 20-60 minutes of CRT with the therapist, 20-60 minutes of work learning how to apply CRT strategies to real life, and 20-60

minutes of independent CRT, done by the patient in their own time. Those in the second group take part in group CRT. This involves taking part in hour long sessions three times a week for 14 weeks in groups of four. At the start of the study, after the CRT programs are complete and then six months later, participants in both groups complete a number of questionnaires in order to evaluate how effective the treatment that they have received has been.

What are the possible benefits and risks of participating?
Participants benefit from receiving financial compensation for taking part in each of the research assessments (£7 per hour). Additionally, all participants will receive cognitive remediation therapy that may help their thinking skills and everyday activities. There are no notable risks involved with participating in this study.

Where is the study run from?
South London and Maudsley NHS Foundation Trust and nine other Mental Health NHS Trusts in England (UK)

When is the study starting and how long is it expected to run for?
January 2016 to March 2021

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

Who is the main contact?
1. Ms Tjasa Velikonja (public)
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Contact information

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Public

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Additional identifiers

Protocol serial number
20362

Study information

Scientific Title
Building Resilience and Recovery through Enhancing Cognition and quality of LIfe in the early PSychosEs (ECLIPSE)- Study 9: Implementation of Remediation into Early Intervention Services

Acronym
ECLIPSE

Study objectives
Study aim as of 21/07/2016:
The aim of this study is to determine the best CRT implementation method for the majority of people in Early Intervention Services as assessed by the degree to which participants have achieved their personal goals (using the Goal Attainment Scale).

Original study aim:
The aim of this study is to determine the feasibility of implementing cognitive remediation therapy (CRT) into routine NHS early intervention services for psychosis and to establish the optimum implementation mode.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Camden and Kings Cross REC, 22/01/2016, ref: 15/LO/1960

Study design
Randomized; Interventional; Design type: Not Specified, Psychological & Behavioural

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Non-affective psychosis

Interventions
Current Interventions as of 03/04/2019:
All participants will be randomised to one of 2 trial arms, to receive either intensive CRT or CRT in a group setting.
Both CRT interventions (intensive/group) will be carried out using computerised cognitive remediation (CIRCUITS Programme). There will be two regimes with different associated hours of therapist contact but all with 42 treatment hours.

Intensive CRT: All participants are offered 10.5 weeks of twice weekly individual therapy. The sessions last for around 60-180 minutes and are in 3 parts:
1. 20-60 minutes of CRT with a therapist
2. 20-60 minutes of in vivo transfer work (i.e. putting CRT strategies into real life) with a therapist
3. 20-60 minutes of independent CRT, set up by the therapist on site, and done off-site in the patient's own time
Each patient receives up to 42 hours of CRT (21 with therapist, 21 independently) and 21 hours of in vivo transfer work (with a therapist).

Group CRT: All participants attend 14 weeks of three times weekly group therapy (up to 42 hours of CRT in total). Participants will join the group as soon as possible following randomisation. Groups have closed membership, with 4 participants per group and each group will have one therapist. Each session lasts for 1 hour, with attendance for at least 20 minutes considered to have completed a session. Group sessions begin and end with group activities, relating to goal-setting and metacognition. During the rest of the session, patients work independently on CIRCuiTS tasks (at the same time) with the therapist offering help and support to individuals on an as-needed basis.

Beside completing a pre-therapy (baseline) assessment in the 4 weeks prior to randomisation, post-therapy interviews/assessments will be conducted immediately following the 14-week intervention and 6 months after therapy using the same list of cognitive, clinical and other measures.

Previous Interventions (as of 15/01/2018):
Consenting patients will be randomised in blocks of 15 stratified by research site at week 0, week 14/15 and week 28/30, with randomisation in proportions 4:4:3:4 (group CRT/independent CRT/ intensive CRT/ treatment-as-usual). Alternative randomisation allocations will be used in the scenario where 15 participants cannot be recruited within the 12-week recruitment period, down to a minimum of 11 participants. This flexibility will allow more efficient use of time and resources (e.g. in case of unexpected participant's withdrawal). All CRT interventions (intensive /group/independent) will be carried out using computerised cognitive remediation (CIRCUITS Programme). There will be three regimes with different associated hours of therapist contact but all with 42 treatment hours.

Intensive CRT group: All participants are offered 10.5 weeks of twice weekly individual therapy. The sessions last for around 60-180 minutes and are in 3 parts:
1. 20-60 minutes of CRT with a therapist
2. 20-60 minutes of in vivo transfer work (i.e. putting CRT strategies into real life) with a therapist
3. 20-60 minutes of independent CRT, set up by the therapist on site, and done off-site in the patient's own time
Each patient receives up to 42 hours of CRT (21 with therapist, 21 independently) and 21 hours of in vivo transfer work (with a therapist).

Group CRT group: All participants attend 14 weeks of three times weekly group therapy (up to 42 hours of CRT in total). The groups have closed membership and include 4 participants per group with one therapist leading the sessions. Each session lasts for 1 hour, with attendance for at least 20 minutes considered have completed a session. Group sessions begin and end with group activities, relating to goal-setting and metacognition. During the rest of the session, patients work independently on CIRCuiTS tasks (at the same time) with the therapist offering help and support to individuals on an as-needed basis.

Independent CRT group: All participants are offered one individual session to get started. Following this, participants are offered up to 41 independent sessions (up to 42 hours of CRT in total). To support the independent sessions, the therapist offers telephone contact and/or attendance at daily drop-in sessions on an as needed basis (estimated average therapist time: 1 hour per fortnight). Drop-in sessions allow participants to attend over a set time period during the day, during which s/he will have access to a work-station, and the therapist will meet with them for about 5 minutes to make sure they have been able to set up a session and have any questions/ problems addressed. The participant then works independently for the rest of the session. Valid sessions last a minimum of 20 and a maximum of 60 minutes.

Treatment as usual group:
Participants receive standard, multi-modal treatment which consists of different therapies as defined as necessary by the treating team.

Beside completing a pre-therapy (baseline) assessment in the 4 weeks prior to randomisation, post-therapy interviews/assessments will be conducted immediately following the 14 week intervention and 6 months after therapy using the same list of cognitive, clinical and other measures.

Previous Interventions:
Consenting patients will be randomised in blocks of 15 stratified by research site at week 0, week 14/15 and week 28/30, with randomisation in proportions 4:4:3:4 (group CRT/independent CRT/ intensive CRT/ treatment-as-usual). All CRT interventions (intensive/group/independent) will be carried out using computerised cognitive remediation (CIRCUITS Programme). There will be three regimes with different associated hours of therapist contact but all with 42 treatment hours.

Intensive CRT group: All participants are offered 10.5 weeks of twice weekly individual therapy. The sessions last for around 60-180 minutes and are in 3 parts:
1. 20-60 minutes of CRT with a therapist
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Group CRT group: All participants attend 14 weeks of three times weekly group therapy (up to 42 hours of CRT in total). The groups have closed membership and include 4 participants per group with one therapist leading the sessions. Each session lasts for 1 hour, with attendance for at least 20 minutes considered have completed a session. Group sessions begin and end with group activities, relating to goal-setting and metacognition. During the rest of the session, patients work independently on CIRCuiTS tasks (at the same time) with the therapist offering help and support to individuals on an as-needed basis.

Independent CRT group: All participants are offered one individual session to get started. Following this, participants are offered up to 41 independent sessions (up to 42 hours of CRT in total). To support the independent sessions, the therapist offers telephone contact and/or attendance at daily drop-in sessions on an as needed basis (estimated average therapist time: 1 hour per fortnight). Drop-in sessions allow participants to attend over a set time period during the day, during which s/he will have access to a work-station, and the therapist will meet with them for about 5 minutes to make sure they have been able to set up a session and have any questions/ problems addressed. The participant then works independently for the rest of the session. Valid sessions last a minimum of 20 and a maximum of 60 minutes.

Treatment as usual group:
Participants receive standard, multi-modal treatment which consists of different therapies as defined as necessary by the treating team.

Beside completing a pre-therapy (baseline) assessment in the 4 weeks prior to randomisation, post-therapy interviews/assessments will be conducted immediately following the 14 week intervention and 6 months after therapy using the same list of cognitive, clinical and other measures.

Intervention Type
Other

Primary outcome(s)
Achievement of goals is measured using the Goal Attainment Scale at baseline, post-CRT and at 6 months follow up

Key secondary outcome(s))
1. Total number of hours of structured activity per week is measured using The Time Use Survey at baseline, post-CRT and at 6 months follow up
2. Costs of health and social care use measured using The Client Service Receipt Inventory at baseline, post-CRT and at 6 months follow up
3. Quality-adjusted life years (QALYs) measured using the EQ-5D at baseline, post-CRT and at 6 months follow up
4. Self-esteem measured using the Rosenberg Self Esteem Scale at baseline, post-CRT and at 6 months follow up

Completion date
31/03/2021

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 03/04/2019:
1. Attending an Early Intervention Service or any individual within 5 years of their first episode of psychosis. At least three months from the onset of the first episode of psychosis.
2. Aged between 16 and 45 years
3. Research diagnosis of non-affective psychosis, i.e. schizophrenia, schizo-affective or schizophreniform disorder;
4. Ability to give informed consent.

Previous participant inclusion criteria (as of 15/01/2018)
1. Attending an Early Intervention Service for at least three months
2. Aged between 16 and 45 years
3. Research diagnosis of non--affective psychosis, i.e. schizophrenia, schizo-affective or schizophreniform disorder
4. Ability to give informed consent

Previous participant inclusion criteria
1. Attending an Early Intervention Service for at least six months
2. Aged between 16 and 35 years
3. Research diagnosis of non--affective psychosis, i.e. schizophrenia, schizo-affective or schizophreniform disorder
4. Ability to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
All

Total final enrolment
377

Key exclusion criteria
Current participant exclusion criteria as of 03/04/2019:
1. Inability to communicate in English sufficiently to participate in cognitive testing
2. Underlying organic/neurological condition affecting cognition (e.g. traumatic brain injury, seizure disorder)
3. Co-morbid diagnosis of learning disability
4. A definitive diagnosis of bipolar disorder

Previous participant exclusion criteria:
1. Inability to communicate in English sufficiently to participate in cognitive testing
2. Underlying organic/neurological condition affecting cognition(e.g. traumatic brain injury, seizure disorder)
3. Co--morbid diagnosis of learning disability

Date of first enrolment
06/06/2016

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South London and Maudsley NHS Foundation Trust
Michael Rutter Centre
Denmark Hill
London
United Kingdom
SE5 8AZ

Study participating centre
Camden and Islington NHS Foundation Trust
4th Floor, East Wing
St Pancras Hospital
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
North East London NHS Foundation Trust
Goodmayes Hospital
157 Barley Lane
Ilford
United Kingdom
IG3 8XJ

Study participating centre
East London NHS Foundation Trust
Trust Headquarters
9 Alie Street
London
United Kingdom
E1 8DE

Study participating centre
Barnet, Enfield and Haringey Mental Health NHS Trust
Block B2
St. Anns Hospital
St Ann's Road
London
United Kingdom
N15 3TH

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Coventry and Warwickshire Partnership NHS Trust
Wayside House
Wilsons Lane
Coventry
United Kingdom
CV6 6NY

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Headquarters
Arundel Road
Worthing
United Kingdom
BN13 3EP

Study participating centre
Norfolk and Waveney Mental Health NHS Foundation Trust
Hellesdon Hospital
Drayton High Road
Norwich
United Kingdom
NR6 5BE

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Cambridge Road
Fulbourn
Cambridge
United Kingdom
CB21 5HH

Study participating centre
South West London and St George's Mental Health NHS Trust
61 Glenburnie Road
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SW17 7DJ

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

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
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/03/2023	06/03/2023	Yes	No
Protocol article	protocol	15/03/2018		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Secondary analysis	01/03/2024	08/07/2025	Yes	No