

Evaluation of cognitive remediation therapy in a specialist inpatient eating disorder service for young people

Submission date 03/08/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/08/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/01/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Anorexia nervosa is an eating disorder where a person keeps their body weight as low as possible. Cognitive Remediation Therapy (CRT) is a treatment for anorexia nervosa that focuses on improving the cognitive (thinking) inefficiencies that underlie the illness (e.g. poor flexibility in thinking styles; details focused approach). There have been promising results regarding its effectiveness for anorexia nervosa in the form of both individual and group therapy. Both clinicians and services users have reported positive feedback. However, there is a lack of studies exploring the use of CRT in children and adolescents with anorexia nervosa. Young people represent a high proportion of people with anorexia nervosa. CRT would positively impact on their cognitive development and also on helping them to reduce the unhelpful thinking styles that could maintain the illness. The first aim of this study is to assess the feasibility of CRT in young people using an individual format and to find out whether CRT improves their thinking styles and ability to see the 'big picture' vs details. The second aim of this study is to explore young people and their parents/carers' experiences of CRT.

Who can participate?

Young people aged 10-18 newly admitted to Rhodes Wood Hospital (Elysium Healthcare) for an inpatient treatment for anorexia nervosa

What does the study involve?

At the beginning of their stay at Rhodes Wood Hospital participants are randomly allocated into an immediate CRT group or delayed CRT group. If they are part of the immediate CRT group participants receive eight CRT sessions (two sessions a week; 45 minutes per session) from the 2nd week to the 5th week of the programme. If they are part of the delayed CRT group they have the same number of sessions from the 7th to the 10th week of the programme. At the end of the CRT sessions participants complete a questionnaire about their experience of CRT. They also complete an assessment in the 1st, 6th and 11th week of the programme. The assessment includes some questionnaires and computer tests. The questionnaires explore how they think, their eating disorder difficulties, and feelings of anxiety and depression. This can take up to 1.5 hours. They can have multiple breaks and are offered support if they need it. The CRT sessions

and the assessments take place in a familiar therapy room in Rhodes Wood Hospital at a time that suits them. The participants' parents/carers complete two questionnaires about their children's social skills and emotions. Some parents/carers are invited to attend a focus group during the 6th or 11th week to talk about their views of their children's experience of CRT. This allows clinicians to further develop the intervention and to tailor it based on the patients' needs.

What are the possible benefits and risks of participating?

CRT involves the use of games and activities appropriate for young people. In other studies young people found some games and activities included in CRT a bit challenging, which can make them feel distressed. Others have found them fun and enjoyable. The trialists will play and do the activities with the young person and will make sure the games are appropriate for them. Young people may find CRT helpful as it aims to improve flexibility in the way they think, helping them to better manage their routine and eating disorder difficulties. The information may also help to improve treatment for eating disorders.

Where is the study run from?

The study is being run by the Institute of Psychiatry, Psychology and Neuroscience – King's College London (UK) and takes place at Rhodes Wood Hospital (Elysium Healthcare), Hatfield, London (UK)

When is the study starting and how long is it expected to run for?

October 2016 to September 2022

Who is funding the study?

Elysium Healthcare (UK)

Who is the main contact?

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Additional identifiers

Protocol serial number
Protocol identification number 07/04/2017 & 1.0

Study information

Scientific Title
Pilot randomized controlled trial of cognitive remediation therapy in a specialist inpatient eating disorder service for children and adolescents

Acronym
CAN-CRT

Study objectives
Being a pilot RCT trial it is hypothesized that:

1. It will be feasible to recruit 80 participants over the planned 36 month recruitment phase, as per power calculation conducted
2. The neuropsychological measures employed in the current study sample will be suitable for use in evaluating individual CRT in an child and adolescent sample (i.e. sensitive to change pre-/post intervention and produce similar variability as found in previous research in both experimental and control group)
3. Standard treatment (TAU) with the addition of Cognitive Remediation Therapy (CRT) is superior to TAU alone for the improvement of set-shifting and central coherence
Significant differences (reflecting positive change) will be demonstrated between pre/post measures at Time 1/Week 1 and Time 2/Week 6 for participants receiving individual CRT (in addition to TAU) at the start of the treatment programme (Immediate CRT Group - Experimental group) relative to those (Delayed CRT group-control group) receiving a delayed individual CRT (in addition to TAU) from Week 7 to Week 11
4. Longer-term effects of CRT will be identified when assessing those who received individual

CRT at the start of the treatment programme (Immediate CRT Group - Experimental group) at Time 3-Week 11

5. Qualitative data gathered through 'Satisfaction Questionnaire of individual CRT session' to be completed by the service users' and focus groups to be attended by carers will inform directions of further development of the intervention

Ethics approval required

Old ethics approval format

Ethics approval(s)

London - Camberwell St Giles Research Ethics Committee, 01/08/2017, ref: 17/LO/0876

Study design

Single-center pilot randomized controlled blinded superiority study with two crossover groups

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anorexia nervosa

Interventions

The present study will be a single-center, pilot, randomized, controlled, crossover-group, superiority study to evaluate the feasibility of eight individual sessions of CRT in a specialist inpatient eating disorder service for children and adolescents. The structure of the CRT is based on the CRT Manual developed by Tchanturia et al. (Tchanturia et al., 2010) and newly developed manual from the Maudsley group for young people (Maiden et al., 2014).

Trial participants will be randomised between two parallel groups in a 1:1 allocation (40 participants per treatment group). A sequential stratified randomisation will allocate participants to treatment groups, with an equal number of participants in each stratification group using an initial randomisation allocation sequence (n cases). Participants will be randomly allocated to one of the two trial arms (Immediate CRT +TAU; Delayed CRT+TAU) within 24 hours of completion of Time 1 assessment. After receiving coded and anonymised data, randomisation will be carried out and managed by a standard statistical package (SPSS/IBM). A database will hold the basic details required for randomization [date of birth, severity of illness (Weight for Height percentage, WfH %), initials and unique patient number]. To minimise bias, a stratified randomisation using date of birth and severity of the illness (WfH %) will be performed. The first n cases (n will not be disclosed) will be allocated randomly to further enhance allocation concealment. Randomisation can only be carried out by the Department of Mathematics, Royal Holloway University, in the person of Teo Sharia and details will be locked following group allocation. The stratification factors (age and illness severity) will be adjusted for in the analysis. Opaque and sealed envelopes will be used for allocation concealment. The research assistants conducting the assessment will not be revealed the treatment conditions. Given the nature of the study design, all patients and therapists are aware of the treatment condition (Immediate CRT or Delayed CRT). Patients are informed that both treatment arms are being investigated as to their potential to enhance subsequent TAU.

The immediate-experimental group receives standard treatment with the addition of eight, twice weekly individual sessions CRT at the start of the treatment programme (Week 2 to Week 5) and TAU only for rest of the duration of the programme.

The delayed-control group receives TAU only at the start of the programme and TAU with the addition of eight, twice-weekly individual sessions CRT in the second part of the programme (Week 7 to Week 10).

A repeated measures design will be conducted at three timepoints: Time 1: Week 1; Time 2: Week 6; Time 3: Week 11.

Intervention Type

Behavioural

Primary outcome(s)

1. Set-shifting (cognitive flexibility), measured with the Wisconsin Card Sorting Task – computerized version (WCST, Heaton et al., 1993) and the Brixton Test at week 1, week 6 and week 11
2. Central coherence, measured with Rey-Osterrieth Complex Figures Task and D-FLEX (Roberts et al., 2011) at week 1, week 6 and week 11

Key secondary outcome(s)

1. Intellectual functioning, assessed using Weschler Abbreviated Scale of Intelligence II Two-subtest version (WASI-II 2 subtest) standardised brief assessment of intellectual functioning (IQ) at week 1
2. Eating disorder symptomatology, assessed using Eating Disorder Examination Questionnaire (EDE-Q) standardised self-report measure of eating disorder psychopathology, validated for use in children and adolescents, at week 1, week 6 and week 11
3. Depression, assessed using Revised Child and Anxiety and Depression Scale (R-CADS) standardised self-report measure of anxiety and depression symptoms, validated for use in children and adolescents, at week 1, week 6 and week 11
4. Motivation and confidence to change, assessed using Motivation Ruler self-report measure of importance and confidence to change using Visual Analogue Scale (0-10), created ad hoc, at week 1, week 6 and week 11
5. Autistic spectrum traits, assessed using Social Communications Questionnaire (SCQ-20 item) standardised measure of Autism Spectrum Disorder traits, completed by parents/guardians, at week 1, week 6 and week 11
6. Presence and severity of social impairment within the autism spectrum, assessed using Social Responsiveness Scale (SRS) standardised measure to identify the presence and severity of social impairment within the autism spectrum and differentiates it from that which occurs in other disorders, at week 1, week 6 and week 11
7. Satisfaction with the intervention, assessed using individual satisfaction questionnaire, created ad hoc, self-report measure for completion at end of intervention. This measure will be adapted to include an 'open feedback' section, in order to enable participants to expand on their thoughts and feedback about the group CRT intervention. Participants are asked to provide their views regarding: what they found beneficial and what challenging; what they enjoyed and what they did not like; whether they were able to transfer some skills in their routine; and suggestions for further improvements of the intervention. This will maximize the involvement of service users' in the development of the intervention. Assessed at the end of the intervention (week 6 for experimental-immediate group; week 11 for delayed-control group)
8. Parents/carer/guardians' perception of the intervention, assessed using focus groups. A group

of eight parents/carers/guardians of experimental immediate group and control-delayed CRT group will be invited to attend a focus group with the aim to explore their views and perceptions of intervention outcomes, barriers to change and suggestions for improvement. Assessed at the end of the intervention (week 6 for experimental-immediate group; week 11 for delayed-control group)

Completion date

01/04/2020

Eligibility

Key inclusion criteria

1. Participants' parents/carers/guardians written, informed consent and participants' informed assent (if below age of 16) informed consent (if above age of 16)
2. Males or females
3. Aged 10-18
4. Diagnosis of AN or atypical AN (according to DSM-V criteria)
5. Newly referred to Rhodes Wood Hospital (Elysium Healthcare)
6. Fluency in English
7. No visual impairment
8. No cognitive impairment
9. No drug or alcohol abuse
10. Absence of severe comorbidity at the time of intake (e.g. psychosis, severe learning disability, brain injury)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 years

Upper age limit

18 years

Sex

All

Total final enrolment

80

Key exclusion criteria

1. No participants' parents/carers/guardians written, informed consent and no participants' informed assent (if below age of 16) and no informed consent (if above age of 16)
2. No English language fluency

2. Visual impairment
3. Drug or alcohol abuse
4. Cognitive impairment
5. Severe comorbidity at the time of intake (e.g. psychosis, severe learning disability, brain injury)

Date of first enrolment

01/09/2017

Date of final enrolment

15/01/2020

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Rhodes Wood Hospital (Elysium Healthcare)

Sheperd's Way

Brookmans Park

Hatfield

London

United Kingdom

AL9 6NN

Sponsor information

Organisation

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Industry

Funder Name

Elysium Healthcare

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

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	Feasibility results	24/11/2021	20/12/2021	Yes	No
Results article	Qualitative results	17/01/2022	17/01/2022	Yes	No
Protocol article	protocol	01/09/2018	01/02/2019	Yes	No
HRA research summary	Participant information sheet		28/06/2023	No	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes