ISRCTN81736780 https://doi.org/10.1186/ISRCTN81736780

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

Registration date
11/08/2017

Overall study status
Completed

Last Edited
17/01/2022

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
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?
1. Dr Lucia Giombini
lucia.giombini@kcl.ac.uk
2. Dr Kate Tchanturia
kate.tchanturia@kcl.ac.uk
3. Dr Abigail Easter
abigail.easter@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Lucia Giombini

Contact details
Rhodes Wood Hospital
Sheperd's Way
Brookmans Park
Hatfield
London
United Kingdom

AL9 6NN
+44 (0)170 729 1500
lucia.giombini@kcl.ac.uk

Type(s)
Scientific

Contact name
Dr Kate Tchanturia

Contact details
PO59 Psychological Medicine
King’s College, London
Institute of Psychiatry, Psychology and Neuroscience
London
United Kingdom
SE5 8AF
+44 (0)207 848 0134
kate.tchanturia@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

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 measure
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

Secondary outcome measures
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)

Overall study start date
01/10/2016

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

Age group
Child

Lower age limit

10 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Overall sample size 80 (immediate CRT-experimental group 40; delayed CRT-control group 40)

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
England

United Kingdom

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)

Sponsor details
Institute of Psychiatry, Psychology and Neuroscience
103 Denmark Hill
London
England
United Kingdom
SE5 8AF
+44 (0)207 848 0134
kate.tchanturia@kcl.ac.uk

Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Industry

Funder Name
Elysium Healthcare

Results and Publications

Publication and dissemination plan
The study protocol will be published after the ISRCTN registration and it will include the statistical analysis plan. Every attempt will be made to reduce to an absolute minimum the interval between the completion of data collection and the release of the study results. Participants involved in the study will be given a departmental newsletter on completion of the study, which will describe the results of the project. Also, a brief layperson report, summarising the main findings of the study, will be written for participants. Participants will have the researchers' contact details and will be able to use these to seek further details of the studies results should they wish to. Report of preliminary findings will be circulated internally for Rhodes Wood Hospital staff members.
Findings of the study will be published in peer-reviewed scientific journals, presented at international conferences, and published on the ISRCTN Registry website. As the trial is conducted as part of PhD course, King’s College London authorship guidelines will be followed.

Intention to publish date

31/12/2021

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