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The effectiveness of cognitive remediation therapy as a component of treatment for anorexia nervosa

Submission date
29/02/2012

Recruitment status
No longer recruiting

Registration date
27/04/2012

Overall study status
Completed

Last Edited
07/04/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Anorexia nervosa is a serious mental health condition where a person keeps their body weight as low as possible. Individuals with anorexia nervosa have been found to have difficulties with cognitive flexibility. Cognitive flexibility is the ability to shift attention. Shifting attention allows individuals to change their thinking and/or behaviour to adapt to changes in the environment. Cognitive Remediation Therapy was designed to improve cognitive flexibility, memory and planning skills through the use of mental exercises, reflection on thinking styles and exploring new ways of thinking in everyday life. Mental exercises include tasks that involve switching attention and estimating. The aims of this study are to investigate the effectiveness and acceptability of Cognitive Remediation Therapy as a component of treatment for anorexia nervosa, and to examine whether Cognitive Remediation Therapy enhances the effectiveness of Cognitive Behavioural Therapy.

Who can participate?
Women aged between 18 and 65 with anorexia nervosa

What does the study involve?
Participants are randomly allocated to either Group 1 or Group 2. Participants in Group 1 receive 6 individual sessions of Cognitive Remediation Therapy followed by 6 individual sessions of Cognitive Behavioural Therapy. They also undergo assessments at the start of the study, after the 6 individual sessions of Cognitive Remediation Therapy, and after the 6 sessions of Cognitive Behavioural Therapy. Group 2 receive 6 individual sessions of Cognitive Behavioural Therapy. They also undergo assessments at the start of the study and after the 6 sessions of Cognitive Behavioural Therapy.

What are the possible benefits and risks of participating?
Participants may feel positive about being involved in research investigating the effectiveness of a new treatment that could benefit future patients. It is hoped that the information gathered will be of value in improving treatment for anorexia nervosa. The time required to participate in the tests may be inconvenient for some participants, but previous studies have found that

participants enjoy the tests. Concentration and attention are required throughout the tests and participants' performance could be adversely affected by fatigue. To reduce the effect of fatigue, participants are offered a break between the tests. Another identified risk is the potential distress of participants. During the tests participants are asked about their eating behaviour and their thoughts/concerns about body shape and weight. The questionnaires are widely used in research and clinical practice with eating disorder patients. There is no evidence to suggest that these tests cause distress, but it is possible that focusing on psychological difficulties may result in some participants experiencing a degree of distress. In the unlikely event that this happens, participants will be encouraged to discuss any upsetting issues with clinical staff within NHS Tayside Eating Disorders Service who are involved in their routine outpatient care. The researcher will liaise with clinical staff and rely on their judgement as to whether specific patients are too emotionally or physically frail to participate. Participation in the study will be confidential, but if there is a risk to the participant or others the researcher will inform a named clinical member of staff within NHS Tayside Eating Disorders Service. This would be discussed with the participant prior to disclosing the information. Only the researcher and her supervisor will have access to identifiable data. Data stored on a computer will be anonymised and password protected.

Where is the study run from?
NHS Tayside (UK)

When is study starting and how long is it expected to run for?
April 2012 to July 2013

Who is funding the study?
NHS Tayside and University of Edinburgh (UK)

Who is the main contact?
Moira Cook

Contact information

Type(s)
Scientific

Contact name
Ms Moira Cook

Contact details
Department of Clinical Neuropsychology
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of cognitive remediation therapy as a component of treatment for anorexia nervosa: a randomised controlled trial

Study objectives
Cognitive remediation therapy will increase the effectiveness of cognitive behavioural therapy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-site randomised controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Anorexia nervosa

Interventions
Group 1 will receive 6 sessions of Cognitive Remediation Therapy (CRT) followed by 6 sessions of Cognitive Behavioural Therapy (CBT).
Group 2 will receive 6 sessions of CBT. Both CRT and CBT interventions will consist of individual 1 hour sessions on a weekly or maximum fortnightly basis.

CRT consists of cognitive tasks aimed at increasing the flexibility of thinking skills, improving holistic thinking skills, reflection of thinking skills and information processing. Each session will be made up of a number of tasks consisting of the following:
1. Stroop tasks
2. Estimation task
3. Card stack task
4. Switching time zones task
5. Switch-attention task
6. Maps task
7. Prioritising task
8. Up and Down task
9. How To task
10. Search and Count task
11. Main ideas task

CBT consists of making the connections between thinking, emotion, behaviour and physiology explicit to individuals through the use of behavioural experiments and guided discovery. The sessions will cover the following topics:
1. Providing education about, and explaining the multiple functions of, anorexic symptomatology
2. Presenting the cognitive rationale for treatment
3. Explaining the rationale and providing advice for restoring normal nutrition and weight
4. Prescribing normalised eating patterns
5. Implementing self-monitoring and meal planning
6. Strategies for interrupting bingeing, purgative and over-exercising behaviours as appropriate
7. Increasing motivation for change
8. Identifying dysfunctional thinking patterns
9. Developing cognitive restructuring skills
10. Modifying concepts of the self
11. Challenging cultural values regarding weight and shape
12. Summarising progress and areas of continued vulnerability
13. Reviewing warning signs of relapse
14. Reviewing fundamentals of continued progress

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Eating Disorders Examination Questionnaire (EDE-Q) (Fairburn & Cooper, 1993)

Secondary outcome measures
1. Wisconsin Card Sorting Test (Heaton, 1981)
2. National Adult Reading Test (NART) (Nelson, 1982)
3. Hayling Sentence Completion Test (Burgess & Shallice, 1997)
4. Brixton Spatial Anticipation Test (Burgess & Shallice, 1997)
5. Delis-Kaplan Executive Function System (Delis, Kaplan & Kramer, 2001)
6. Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983)
7. Social Problem Solving Inventory Revised (SPSI-R) (D'Zurilla, Nezu & Maydeu-Olivares, 1999)
8. Obsessive Compulsive Inventory (Foa, Kozak, Salkovskis, Coles & Amir, 1998)

9. Perfectionism, Perseveration and Persistence Questionnaire (Serpell, Waller, Fearon & Meyer, 2009)

Overall study start date
01/04/2012

Completion date
31/07/2012

Eligibility

Key inclusion criteria
1. Female, aged 18-65
2. English as first language
3. Meet International Classification of Diseases, Tenth Revision (ICD-10) criteria for a diagnosis of anorexia nervosa or atypical anorexia nervosa
4. Receiving outpatient treatment within NHS Tayside Eating Disorders Service

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
40

Key exclusion criteria
1. Deemed by clinical staff to be too emotionally or physically frail to participate
2. Current psychosis
3. History of Learning Disability/Developmental Disorder
4. History of head injury involving loss of consciousness
5. History/current neurological disorder
6. Uncorrected significant visual or motor impairment
7. Current/previous substance misuse
8. Administrated neuropsychological measures in the past - knowledge of neuropsychological measures

Date of first enrolment
01/04/2012

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Ninewells Hospital
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
NHS Tayside Health Board (UK)

Sponsor details
c/o Dr Vera Nuritova
Ninewells Hospital and Medical School
Tayside Medical Science Centre Research and Development Office
Residency Block, Level 3
George Pirie Way
Dundee
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DD9 1SY

Sponsor type
Hospital/treatment centre

Website
http://www.nhstayside.scot.nhs.uk/

ROR
https://ror.org/000ywep40

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Tayside (UK)

Funder Name
University of Edinburgh (UK)

Alternative Name(s)
Universitas Academica Edinburgensis, Oilthigh Dhùn Èideann, The University of Edinburgh, University of Edinburgh in United Kingdom, Edin, Tounis College, King James' College, Athens of the North, ED, Edin

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration