Cognitive Remediation Therapy (CRT) as a treatment enhancer in eating disorders and obsessive compulsive disorders

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44074

Source
ToetsingOnline

Brief title
Cognitive Remediation Therapy in eating disorders and OCD

Condition

- Other condition
- Eating disorders and disturbances

Synonym
Eating Disorders and Obssessive Compulsive Disorders

Health condition

én obssesieve compulsieve stoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Altrecht GGZ (Den Dolder)
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW

Intervention

Keyword: Cognitive_flexibility, Cognitive_remediation_therapy, Eating_Disorders, Obsessive_Compulsive_Disorders

Outcome measures

Primary outcome

-Disease specific psychopathology

-Quality of ife and daily functioning

-Treatment adherence

-Cost effectiveness (direct medical costs, indirect costs due to health

problems)

Secondary outcome

-Cognitive flexibility

-General psychopathology

Study description

Background summary

Obsessive Compulsive Disorders (OCD) and Eating disorders (ED) are *according to the WHO - among the most incapacitating and costly of all mental disorders. Cognitive behavior treatment and/or medication have proven to be only moderately successful in both disorders in between 40% and 60% of patients, leaving much room for more effective treatment algorithms. A striking underlying deficit shared by both disorders is patients' cognitive inflexibility, a trait that is likely to hamper treatment engagement and ability to benefit from treatment. New promising evidence indicates that Cognitive Remediation Therapy (CRT), an easy-to-use technique, successfully enhances flexible thinking styles, and therefore enhances benefit from

symptom-based therapies, and improvement of quality of life. Although not investigated directly, CRT-like strategies have also been effective in enhancing symptom reduction in OCD.

Study objective

The objectives of this study are: 1) To investigate the treatment enhancing effect of CRT in anorexia nervosa/eating disorders not otherwise specified - subtype anorexia nervosa and OCD (i.e to what extent does CRT lead to shorter duration of treatment, increased symptom reduction and quality of life, reduced dropout rates?) 2) To investigate neurocognitive markers of treatment enhancement by CRT in OCD and ED, i.e. which characteristics determine for which patients augmentation with CRT is most beneficial in clinical practice? 3)To investigate cost effectiveness and budget impact of CRT on treatment of ED and OCD

Study design

This controlled multicenter trial involves 64 adult patients with ED (anorexia nervosa/eating disorders not otherwise specified - subtype anorexia nervosa), and 64 patients with OCD, randomized to 10 bi-weekly sessions with either CRT or a control condition, followed by TAU which will involve ao weekly sessions of 60-90 minutes CBT. Additionally, a control group will be included who will be asked to do the baseline assessment but not the other assessments. Treatment effect will be analysed using linear mixed model analyses including calculations of clinically significant change. A Markov modeling approach will be applied for the economic evaluation. Cost utility analyses will be performed from a societal perspective estimating the cost per QALY. The budget impact analysis will be conducted from a payers and societal perspective. Disorder-specific symptom severity (EDEQ; YBOCS severity scale), Quality of Life (EQ-5D), cognitive flexibility (D-flex), healthcare use costs, budget impact, and loss of work productivity will be assessed at baseline, post CRT, and after 6 and 12 months (or end of treatment) TAU.

Intervention

Cognitive Remediation Therapy (CRT): CRT consists of ten individual sessions (45 minutes each), given within six weeks. These CRT sessions are delivered by trained professionals (therapists, clinical nurses). CRT uses a range of cognitive (paper and pencil) exercises that are specifically aimed at improving cognitive flexibility and increasing global information processing as opposed to detail-oriented processing. Also CRT aims to improve the awareness of ongoing thinking patterns. Reflection about thinking styles during these cognitive exercises is a crucial part of CRT. Patients are also encouraged to find out how these thinking styles affect their daily life and from about the sixth session onwards, the cognitive exercises are linked to real life

behavioral tasks. These behavioral tasks are designed to allow patients to practice skills in daily life, thereby introducing more flexible behavior in their everyday life. A CRT manual is adapted for eating disorders by Tchanturia et al.2010.

Supportive Counseling Therapy: The placebo treatment condition will entail 10 bi-weekly individual sessions of 45 minutes duration, delivered by psychologists or trained nurses, adapted from the placebo treatment developed by Bryant et al. (1998), called: nondirective supportive counseling (SC). This placebo treatment condition has been used ao in treatment studies of acute stress disorder. In the first treatment session the rationale of nondirective supportive counseling will be explained. The subsequent SC sessions will entail 1) education about mental disorders in general, 2) general problem solving skills, and uncondiotnal support. Further, the patients are encouraged to keep a diary of current problems and mood
scales (with similar load as for the assignments in CRT). If the patient raises an issue with respect to his/ her mental illness, treatment goal to be achieved, inter relational issues or psychosocial situation, no explanations nor any direct advice is given. The sessions are audiotaped to check for treatment integrity (therapeutic ingredients).

Study burden and risks

Riscs are minimal for this study and only related to the research assessments. Patients are, seeing the TOPGGz status of each of the participating centres, used to completing questionnaires and doing computertasks. Patients are also used to answering questions about their symptoms and problems.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

ED patients: The ED patients encompass primarily patients with Anorexia nervosa (including those patients that meet some but not all of the diagnostic criteria for AN who are diagnosed as Eating Disorders Not Otherwise Specified ((clinically referred to as AN) as established by medical experts and verified with the Structured Clinical Interview on axis I DSM V diagnoses (SCID-I; for a structural diagnosis)/ assessed with the aid of the Eating Disorder Examination Interview.;OCD patients: The OCD patients encompass OCD patients of all symptom dimensions (Leckman, Grice, Boardman et al., 1997), as established by medical experts and verified with the Structured Clinical Interview on axis I DSM IV diagnoses (SCID-I; for a structural diagnosis) and should have a Yale- Brown Obsessive-compulsive scale (Goodman, Price, Rasmussen et al., 1989a,1989b) severity score of > 16.;Control participants: The control participants encompass only adult people of whom 50% is matched to the ED patient group and 50%.to the OCD patient group regarding gender and age

Exclusion criteria

Patients with neurological illness (epilepsia, Parkinson*s disease), co-morbid severe psychiatric disorders (severe major depressive disorder, current psychosis, dependence and abuse of alcohol, drugs), mental deficiency (IQ < 80) and inability to adequately read or speak Dutch will be excluded. Use of anti-depressants will be permitted, provided that dosages are kept constant during the experimental part of the study. Benzodiazepine use will be accepted only when used as sleep medication, since benzodiazepine use might hamper the effect of cognitive treatments.
Control participants with a current episode or history of psychiatric disorders as determined with the MINI interview, with neurological illness, mental deficiency, or an inability to adequately read of speak Dutch will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2013
Enrollment:	192
Type:	Actual

Ethics review

Approved WMO Date:	27-09-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43751.041.13