Psychological treatment of Eating Disorders:
A multi-centered randomized controlled trial on the (cost-)effectiveness of Enhanced Cognitive Behavior Therapy (CBT-E)

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24839

Source
NTR

Health condition

Eating Disorders. Anorexia Nervosa. Bulimia Nervosa, Binge Eating Disorder.

Sponsors and support

Primary sponsor: Parnassia Group/PsyQ Haaglanden/ department of eating disorders
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

Recovery from Eeating Disorder (SCID-I)

Secondary outcome

Secondary outcome measures include eating disorder psychopathology (EDEQ), screening for common mental disorders (WSQ), anxiety and depressive symptoms (MASQ), self-esteem (RSE/IAT), perfectionism (F-MPS), interpersonal problems (IIP-32), health related quality of life (EQ-5D,SF-36), health care use, productivity loss (TIC-P). Tertiary outcome measures, including self-esteem (RSE/IAT), perfectionism (F-MPS) and interpersonal problems (IIP-32), will be used to determine mediators, which can mediate the effect of the treatment.

Study description

Background summary

Rationale: This is the first cost-effectiveness study of Enhanced Cognitive Behavior Therapy (CBT-E). Initial research in the UK suggests that CBT-E is more effective than the earlier version of CBT with eating disorders, especially Boulimia Nervosa (BN) and Eating Disorder Not Otherwise Specified (EDNOS). CBT-E has yet to be evaluated in other countries, like the Netherlands. The results from this multi-center study - with 3 sites specialized in eating disorders (PsyQ Haaglanden, PsyQ Groningen and Altrecht (Rintveld) - will deliver the foundations for an update of the Dutch Multidisciplinary Guidelines Eating Disorders.
Objective: To assess the (cost-)effectiveness of Enhanced Cognitive Behavioral Therapy (CBT-E) compared to Treatment as Usual (TAU) for patients with an Eating Disorder (ED).
Study design: Multi-center RCT.
Study population: 132 Adult outpatients (from age 18) with an ED diagnosis (SCID-I) and a 17.5 < BMI <40.
Intervention (if applicable): 20 CBT-E sessions.
Main study parameters/endpoints: The primary outcome measure is recovery from ED (SCID-I). Secondary outcome measures include eating disorder psychopathology, screening for common mental disorders, anxiety and depressive symptoms, self-esteem, perfectionism, interpersonal problems, health related quality of life, health care use, productivity loss and caregiver burden. Tertiary outcome measures, including self-esteem, perfectionism and interpersonal problems, will be used to determine mediators, which can mediate the effect of the treatment.

Study objective

We expect that CBT-E will be preferred over TAU in terms of:

Direct clinical effectiveness: higher percentage of recovery from ED
Indirect clinical effectiveness: Improved health related quality of life. Improvement in related problem areas (self-esteem, depression)
Direct costs: Lower number of mental health care contacts and consequently treatment

costs. Lower utilization of other health care and consequently costs. Less costs outside the health care e.g. travel and waiting time, out-of-pocket expenditures.
Indirect costs: Less absence from work. Less reduced efficiency.

Study design

T0= baseline measurement; T1=after session 9 CBT-E/5 weeks after start treatment TAU; T2= posttreatment CBT-E/20 weeks after start treatment TAU; T3= at 20 weeks follow up CBT-E/40 weeks after start of treatment TAU; T4= at 60 weeks follow up CBT-E/80 weeks after start treatment TAU

Intervention

Condition 1: Cognitive Behavioral Therapie-Enhanced (CBT-E). CBT-E is the enhanced version of CBT and is designed to be suitable for the full range of ED diagnoses. It is based upon the transdiagnostic theory of the maintenance of EDs in which it is held that most of the mechanisms involved in the persistence of EDs are common to all three EDs rather than being peculiar to any one diagnostic group. CBT-E uses new strategies and procedures to address mechanisms that are central to the maintenance of EDs (e.g., procedures directed at over-evaluation of shape and weight). CBT-E consists of 20 treatments sessions over 20 weeks
Condition 2: Treatment as Usual (TAU). The usual treatment given at the site, in general based on Cognitive Behavior Therapy. Depending on the site’s treatment policy, this may vary from low intensity care to high intensity care. The type of treatment provided is registered.

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Eligibility criteria

Inclusion criteria

- Adult outpatients (from age 18) with an ED diagnosis, AN, BN, EDNOS (SCID-I, with additional proposed DSM-5 criteria for BED) and a 17.5 < BMI <40
- Informed consent

Exclusion criteria

- Prior receipt of a treatment closely resembling CBT-E or an evidence-based treatment for the eating disorder in past two years.
- An axis 1 psychiatric disorder that makes the treatment impossible (e.g. psychoses, addiction)
- Medical instability/pregnancy
- Not available for the coming 20 weeks
- Patients who are receiving ongoing psychiatric treatment (exception for antidepressant medication)
- Suicidality
- Problems with Dutch language (talking, reading, writing)
- Mental deficiency

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-05-2013

Enrollment:	132
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39403
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4345
NTR-old	NTR4485
CCMO	NL39205.058.12
OMON	NL-OMON39403

Study results