Psychological treatment of Eating Disorders:
A multi-centered randomized controlled trial on the (cost-)effectiveness of Enhanced Cognitive Behavior Therapy (CBT-E)
Titel for patients: Effectiveness study on the therapy of eating disorders

Published: 19-04-2013
Last updated: 28-09-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eating disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON39403

Source
ToetsingOnline

Brief title
(Cost-)effectiveness study of CBT-E

Condition

- Eating disorders and disturbances

Synonym
Eating Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CBT-E, Cognitive Behavior Therapy, Cost-effectiveness, Eating Disorders

Outcome measures

Primary outcome

The primary treatment outcome measure is the post treatment Eating Disorder level. This is assessed with the SCID-I.

Secondary outcome

Secondary treatment outcome measures are the level of eating disorder pathology (EDE-Q), the presence of common mental disorders (WSQ), self-esteem (RSE/ IAT), perfectionism (F-MPS), interpersonal problems (IPP-32) and anxiety and depression symptoms (MASQ). The cost-effectiveness measures are health related quality of life (EQ-5D and SF-36), service receipt and productivity losses (TiC-P; SF-HLQ), including use of mental and primary health care, social services, out-of-pocket expenditures, travel costs and waiting time (TiC-P; SF-HLQ). The CarerQoL is used to measure and value the subjective burden of informal care in terms of well-being.

Study description

Background summary

Currently, cognitive behavior therapy (CBT) is the treatment of first choice according to the Dutch Multidisciplinary Guideline
Eating Disorders (2006). Effectiveness studies of CBT are scarce, especially in the Netherlands. International research focused
on relatively small categories of EDs (BN or BED). Thus the evidence for this treatment needs to be expanded.
Fairburn developed a relatively short (20 sessions in 20 weeks) transdiagnostic version of CBT, CBT-E(nhanced), 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. According to Fairburn, EDs have more similarities than differences, especially the core
psychopathology (over-evaluation of shape and weight) and expression in attitudes and behavior. CBT-E, the enhanced
version of CBT, 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).

Study objective

The objective of this project is to assess whether CBT-E is more optimal in terms of (cost-)effectiveness than TAU in the
treatment of outpatients with an ED. The results of this study will provide evidence whether or not CBT-E should be delivered to
patients with a broad range of ED diagnoses.
We expect that CBT-E will be preferred over TAU in terms of:
* Direct clinical effectiveness:
o higher percentage of recovery from ED (SCID-I)
* Indirect clinical effectiveness:
o improvement in eating disorder psychopathology
o improved health related quality of life
o improvement in related problem areas (self-esteem, depression)
* Direct costs:
o lower number of mental health care contacts and consequently treatment costs
o lower utilization of other health care and consequently costs
o less direct costs outside the health care e.g. travel and waiting time, out-of-pocket expenditures
* Indirect costs:
o less absence from work
o less reduced efficiency

o less burden to the caregiver
*Mediating effects:
o Self-esteem, perfectionism and interpersonal problems can be determined as mediators for the effect of the treatment

Study design

Multi-centre RCT. The study will be performed at three specialized Eating disorder treatment centers: PsyQ The Hague (Parnassia Psychiatric Institute), PsyQ Groningen (Lentis), Rintveld (Altrecht). 140 Patients meeting in/exclusion criteria are randomly allocated to TAU or CBT-E. Allocation of the patient is done by a central independent research assistant after screening and checking the in/exclusion criteria and signing of the informed consent. Repeated assessments are carried out pre treatment (T0), after session 9 CBT-E/5 weeks after start of treatment TAU (T1), post treatment CBT-E/20 weeks after start of treatment TAU (T2), at 20 weeks follow up CBT-E/40 weeks after start of treatment TAU (T3) and at 60 weeks follow up CBT-E/80 weeks after start treatment TAU (T4). Before start of treatment, at T2 and T4 the structural interview (SCID-I) is carried out to obtain the eating disorder diagnosis. To assess treatment integrity and competence, a random sample of audio taped sessions will be assessed by independent raters.

Intervention

CBT-E versus TAU. TAU is the usual treatment given at the site. 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.

Study burden and risks

No risks are associated with participation. The burden of the research will be 5 assessments of 60 minutes during 80 weeks and three structured interviews for the eating disorder diagnosis (duration 15 minutes). These assessments consist of 10 questionnaires, which the participants can fill in at home at a computer, the interviews will be done by telephone. No benefits are associated with participation, only enhancement of the scientific knowledge.

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

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

Exclusion criteria

The patients who will be excluded will be those whose current clinical state or circumstances make it inappropriate for them to enter treatment experiment (e.g., those at high medical or suicidal risk, psychoses), or patients who are not available for the coming 20 weeks. (For specific exclusion criteria see Research Protocol page 15).

Study design

Design

Study phase: 3

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):	02-06-2013
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO

Date:	19-04-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	17-07-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24839
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL39205.058.12