Online Cognitive Behavioral Therapy-Enhanced for Binge Eating Disorder

Published: 26-08-2019
Last updated: 09-04-2024

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

Summary

ID

NL-OMON48265

Source
ToetsingOnline

Brief title
BED- online

Condition

- Eating disorders and disturbances

Synonym
Binge eating disorder, Eating disorder

Research involving
Human

Sponsors and support

Primary sponsor: Arkin (Amsterdam)
Source(s) of monetary or material Support: particulier fonds en Arkin

Intervention

Keyword: Binge Eating Disorder, Cognitive Behavior Therapy - Enhanced, eHealth, Randomized Control Trial

Outcome measures

Primary outcome

The main study parameter is to compare the efficacy of GSH CBT-E on the amount of binge free days pre- and post-treatment. Primary parameter will be measured through the Eating Disorder Examination (EDE) and Eating Disorder Examination Questionnaire (EDE-Q). All questionnaires will be assessed at start and end of treatment. In week 5, 24 and 36 the EDE-Q will also be conducted.

Secondary outcome

Secondary parameter is eating disorder pathology pre and post treatment. Tertiary parameter are cost effectiveness of GSH CBT-E, quality life and clinical impairment. Secondary parameter will be measured through the Eating Disorder Examination (EDE) and Eating Disorder Examination Questionnaire (EDE-Q). Secondary parameters will also be measured 4 weeks after start of treatment and at 3 and 6 months follow up through the EDE-Q. Tertiary parameters will be measured through the questionnaire on Costs associated with Psychiatric illness (TiC-P), the Quality of life questionnaire (EQ-5D-5L), the Clinical Impairment Assessment (CIA) and Working Alliance Inventory (WAI). All questionnaires will be assessed at start and end of treatment. In week 5 the EDE-Q and CIA will be conducted. During week 24 and 36 only the EDE-Q, EQ-5D-5L, TiC-P, and CIA will be conducted. Followed module will serve as a moderator.

Study description

Background summary

Self-help (SH) interventions based on CBT have proven effective for the treatment of eating disorders in the past when compared to waiting lists. Cognitive behaviour therapy enhanced (CBT-E) has proven to be effective in order to treat eating disorders. However it still remains unknown if a guided self-help (GSH) version of CBT-E (GSH CBT-E) intervention is effective in treatment of binge eating disorder in comparison to a waiting list condition. Therefore an online guided self-help treatment is developed. This treatment is based on CBT-E (GSH CBT-E). It*s hypothesized that GSH CBT-E is superior to the waiting list condition.

Study objective

GSH CBT-E is an internet-based guided self-help intervention. Objective of this study is to investigate the effectiveness of GSH CBT-E in comparison with a waiting list condition on frequency of binge eating (BE). Secondary objective is to measure eating disorder pathology. Tertiary objective is to measure cost-effectiveness of GSH CBT-E, quality of life, clinical impairment and therapeutic alliance.

Study design

Effectiveness of GSH CBT-E in comparison with a waiting list condition will be measured through a Randomized Controlled Trial (RCT). This RCT will be conducted in a routine healthcare practice. 180 participants will participate in this study. Parameters will be measured at start of treatment (week 0), week 5, end of treatment (week 12) and at week 24 and week 36. Week 24 and 36 are follow up measurements.

Intervention

GSH CBT-E is a guided self-help version of CBT-E based on the self help-book *Overcoming Binge Eating*. Treatment period is 12 weeks. Once a week there will be a therapy session of 20 minutes. All sessions will be conducted by phone.

Study burden and risks

Participants burden is expected to be as following:

Burden during *treatment as usual*:
Initial session: 75 minutes
Advisory session: 30 minutes

Conduct of questionnaires: maximum of 3x30 minutes= maximum of 90 minutes
Behandeltijd: 12x 20 minuten= 240 minuten

Total burden during *treatment as usual*: 435 minutes

Extra burden due to study participation:
Conduct of interview: 2x 60 minutes= 120 minutes
2x follow up measurement: 2x maximum 30 minutes= 60 minutes
Totale extra burden: 180 minutes
Total burden of *treatment as usual* and study participation: 180+435= 615 minutes

Contacts

Public
Arkin (Amsterdam)

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Binge Eating Disorder or Other Specified Eating Disorder (OSFED), most similar to Binge Eating disorder diagnosis
2. Age >= 18
3. 19.5 <= BMI < 40
4. Moderately proficient in Dutch
5. Willing to provide contact details including (mobile)phone number
6. Referral letter from their general practitioner (GP)
7. Internet access
8. Computer/tablet at home and willingness to use this for treatment and research purposes
9. Ability to buy *Overcoming binge eating* written by Christopher Fairburn. In case the participant is not able to buy the book, Novarum will provide an exemplar during treatment.
10. Informed consent regarding the study provided by the patient
11. Medication that might influence eating behavior such as, Lithium, Mitrazepine and anti- psychotic stimulants

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Acute psychosis
2. Acute depression
3. Suicidal ideation
4. Self induced vomiting as compensatory behavior
5. Receivement of treatment for ED during the past months
6. Pregnancy
7. Expected absence during treatment period
8. Bariatric surgery

Study design

Design

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

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-09-2019
Enrollment:	180
Type:	Actual

Medical products/devices used

Generic name:	Software
Registration:	No

Ethics review

Approved WMO Date:	26-08-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL69598.100.19