Online Cognitive Behavior Therapy Enhanced for Binge Eating Disorder

No registrations found.

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

Summary

ID

NL-OMON21268

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Binge eating disorder, other specified eating disorder BED

Sponsors and support

Primary sponsor: This intervention will be applied at Novarum center for eating disorders and obesity, the eating disorder department of Arkin
Source(s) of monetary or material Support: An anonymous private funder provided a grant for this study

Intervention

Outcome measures

Primary outcome

The primary outcome measure will be difference in eating disorder pathology, operationalized as the amount of days binge eating occurred, post treatment versus the waiting list control condition.

Secondary outcome

As secondary outcomes, differences in other eating disorder pathology defined as restraint eating, dieting, weight concern and shape concern (C. G. Fairburn & S. J. Beglin, 2008; Cooper & Fairburn, 1987), Quality of Life and clinical impairment will be assessed.

Study description

Background summary

Binge eating disorder is characterized by recurrent episodes of binge eating accompanied by a sense of lack of control. Of the different treatments available, Cognitive Behavior Therapy-Enhanced (CBT-Enhanced) and guided self- help treatment are recommended. As online treatment offers several additional advantages, we have developed a CBT-Enhanced online guided self-help intervention. The aim of this study is to determine whether this intervention reduces eating disorder pathology and increases the amount of binge free days in male and female adults classified with binge eating disorder or other specified eating disorder BED, compared to an untreated waiting list condition. The experimental condition is hypothesized to be superior to the waiting list condition.
The efficacy of an online guided self-help intervention for binge eating disorder will be assessed by conducting a randomized controlled trial. The trial will target male and female adult binge eating disorder patients with a BMI between 19.5 and 40, referred to a specialized eating disorder treatment center. Dual arm allotment will be performed in a 1:1 ratio stratified for BMI above or below 30. Randomization will be blinded to the online intervention (n = 90), or to the control waiting list condition (n = 90). Blinded assessments will be administered at baseline, week 5, at end-of-treatment, and at 12 and 24 weeks follow-up. The primary outcome will be eating disorder pathology, operationalized as number of days on which binge eating occurred. Secondary outcome measures will target other be differences in other eating disorder pathology, clinical impairment due to the eating disorder and quality of life, while therapeutic alliance, demographic characteristics and followed treatment module will serve as effect moderators. Direct treatment costs of the intervention will also be evaluated. Recruitment, assessment and first therapy sessions will start in September 2019.
An online Guided Self-Help Cognitive Behavior Therapy- Enhanced intervention for individuals classified with binge eating disorder or other specified eating disorder. Efficacy will be examined through a Randomized Controlled Trial.

Study objective

It is hypothesized that GSH CBT-E is superior to the waiting list condition with regard to a decrease in eating disorder pathology and clinical impairment. GSH CBT-E is also expected to be superior to the waiting list with regard to increase in the number of binge free days and quality of life.

Study design

The control group will start treatment after a waiting list period of 12 weeks, the same duration as the intervention. After baseline (T0), assessments will take place four times during and after treatment: at week 5, which is the evaluation-point of treatment for GSH CBT-E (T1); at the end of treatment for GSH CBT-E/ start of treatment for waiting list control group (week 12, T2); at 12 weeks after treatment for GSH CBT-E/ End of treatment for the waiting list condition (week 24, T3); and at 24 weeks after treatment for GSH CBT-E/, 12 weeks after treatment for waiting list control group (week 36, T4).

Intervention

GSH CBT-E is a 12 week program. Patients have to start reading information online, to monitor their eating behavior, and to schedule, once a week, weighing, and, twice a week, self- evaluation sessions. A few days after start of treatment, patients will have a 20 minutes phone session with their therapist. To ensure consistency between therapists, these phone sessions are pre-scripted. During the first 4 weeks, patients will have to monitor their eating behavior, including their thoughts and feelings and establish a regular eating pattern. They will also introduce alternative activities for binge eating and work on problem-solving skills. During week 5, they will fill out assessment questionnaires, sent to them by a link, and their progress will be assessed, by both themselves and their therapist. This session will enable them to decide whether to add a module on body evaluation or eating rules during week 6-11 in addition to monitoring, regular eating, alternatives for binge eating and problem solving (figure 2). Before the 12th session patients will have to fill out the questionnaires. Results will be discussed during session 12, when they will also discuss what to do to prevent set-backs. The post treatment EDE will be conducted by phone. GSH CBT-E treatment will not be altered or interfered with during the study. As GSH CBT-E is a 100% guided self- help treatment without face to face sessions, sessions will only be conducted by phone.

Contacts

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Eligibility criteria

Inclusion criteria

(1) a DSM- 5 BED or OFSED most similar to BED classification;
(2) age at least 18;
(3) a BMI between 19.5 and 40;
(4) moderate proficiency in Dutch and ability to read pPart one of the Dutch translation of Overcoming Binge Eating, by Christopher Fairburn (2013) , which involves psychoeducation;
(5) willingness to provide contact details, including phone number, internet access, possession of a computer or tablet, and willingness to use it for treatment and research purposes.

Exclusion criteria

(1) acute psychosis, assessed via Structural Clinical Interview by the DSM 5 (SCID -5) (First, Williams, Karg & Spitzer, 2016);
(2) acute depression, assessed via SCID -5;
(3) suicidal ideation, assessed via SCID -5 or
(4) self-induced vomiting as compensatory behavior, as reported at initial session or EDE-interview at baseline. Other exclusion criteria are:
(5) having received eating disorder treatment during the past 6 months,
(6) being pregnant
(7) reported use of medication with the potential to influence eating behavior such as, Lithium, Mitrazepine and anti- psychotic stimulants.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	27-08-2019
Enrollment:	180
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	27-08-2019
Application type:	First submission

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
NTR-new	NL7994
Other	METC MEC-U : R19.035

Study results