Online Cognitive Behavioral Therapy-Enhanced: Guided self-help versus screen to screen for Binge Eating Disorder, A Randomized Controlled Trial

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

Summary

ID

NL-OMON51181

Source
ToetsingOnline

Brief title
Online guided self-help versus screen tot screen for Binge Eating Disorder

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: Arkin

Intervention

Keyword: Binge Eating Disorder, Cognitive Behavioral Therapy - Enhanced, eHealth, Guided self-help, screen-to-screen

Outcome measures

Primary outcome

The main study parameter is to compare the relative treatment efficacy of guided self-help CBT-E versus screen-to-screen CBT-E, reported as robust remission pre- and post-treatment and during follow-up. The primary parameter will be measured through the Eating Disorder Examination (EDE) and Eating Disorder Examination Questionnaire (EDE-Q) at start and end of treatment and 60 weeks follow up, during follow up, 20, weeks post treatment (week 40) by the EDE-Q.

Secondary outcome

Secondary parameters are the efficacy with regard to clinical impairment and quality of life of guided self-help CBT-E in comparison with screen-to-screen CBT-E after treatment and during follow-up and, to investigate the moderating effect of severity of body dissatisfaction and the association of early menarche and body dissatisfaction. Secondary parameters involving quality of life, clinical impairment and body dissatisfaction will be measured at start and end of treatment, during follow up (20, 60 weeks post treatment) by the EQ-5D-NL, Clinical Impairment Assessment (CIA) and, Body Shape Questionnaire (BSQ). The association between body dissatisfaction and early menarche will be measured at start of treatment. Other parameters are the moderating effects of

therapeutic alliance between both conditions and the compare cost- efficacy.

Therapeutic alliance will be measured by the Working Alliance Inventory and

costs by the questionnaire on Costs associated with Psychiatric illness (TiC-P)

during week 5, 12 and at end of treatment.

Study description

Background summary

Cognitive Behavioral Therapy- Enhanced (CBT-E) is an evidence based and effective treatment for all eating disorders. Offering treatment remotely has several advantages for the patient such as removal of geographical barriers, sessions can be held within the patients safe environment, they can communicate with their therapist wherever they are, and reduced travel costs and travel time. The Covid-19 pandemic increased the urgence of offering specialized treatment remotely and several outpatient centers introduced potential adaptations to their existing levels of care, including CBT-E. There is a lack of studies examining remote versions of CBT-E and no study has directly compared efficacy of guided self-help CBT-E with screen-to-screen CBT-E and investigated the effect of treatment dose. At Novarum center for eating disorders in the Netherlands both CBT-E treatments will be offered online. One treatment protocol will be developed involving a screen-to-screen version of CBT-E (screen-to-screen CBT-E) and another one involves a guided self-help treatment protocol (guided self-help CBT-E). It*s hypothesized that screen-to-screen CBT-E is superior to guided self-help CBT-E and, that guided self-help CBT-E is superior in terms of cost-efficacy.

Study objective

This study compares the efficacy of guided self-help CBT-E with to screen-to-screen CBT-E in terms of robust remission at end of treatment and during follow up. Robust remission will be defined as eating disorder pathology below a clinical cut-off and no binge eating pathology. Secondary objective is to measure the efficacy with regard to clinical impairment and quality of life of guided self-help CBT-E in comparison with screen-to-screen CBT-E group after treatment and during follow-up and, to investigate the moderating effect of severity of body dissatisfaction and the covariating effect of early menarche, as early menarche is expected to be associated with body dissatisfaction.

Study design

A single center randomized controlled trial assessing the effects of the newly developed screen-to-screen CBT-E compared with guided self-help CBT-E. Both treatments are based on Cognitive Behavioral Therapy- Enhanced treatment protocol and will be offered online. Stratification will take place based on BMI group; 19.5 <= BMI <= 35 or 35< BMI <= 40.
180 participants (142= without correction) will participate in this study. Parameters will be measured at start of treatment (week 0), week 5, end of treatment (week 12 for guided self-help, week 20 for screen-to-screen CBT-E), follow up measurements are 20and 60 weeks after end of treatment.

Intervention

Cognitive Behavorial Therapy-Enhanced (CBT-E) is an evidenced based treatment for eating disorders. Treatment period is 20 weeks, including 20 sessions of 50 minutes each. The first 4 weeks will involve 8 sessions, weeks 5- 14 involve weekly sessions and week 15-20 involves bi- weekly sessions. Sessions will be conducted in a screen-to-screen setting. Guided self-help CBT-E is an online guided self-help version of CBT-E based on the self-help book *Overcoming Binge Eating*. Treatment period is 12 weeks and patients will complete exercises at an online treatment platform on a daily basis. Once a week they will have a therapy session of 20 minutes offered through video call.

Study burden and risks

Participants burden is expected to be limited since they receive either screen-to-screen CBT-E or guided self-help CBT-E which is less extensive. Participants will be requested to complete questionnaires at baseline, during and at end of treatment which will be used as treatment evaluation and are therefore also included without study participation. Completion of the self-report follow up measures will be 30 minutes each, 60 minutes in total to complete all follow-up measures. Completion of the interviews will take 3 times 45-60 minutes. In total a burden of maximum 180 minutes for each participant in comparison with treatment without study participation. There are minimal risks associated with participation in this study as the medical device is classified as a class 1 medical device.

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

1. binge eating disorder or other specified feeding or eating disorder (OSFED) binge eating disorder classification
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 read *Overcoming binge eating* written by Christopher Fairburn
10. Informed consent regarding the study provided by the patient

Exclusion criteria

1. Acute psychosis, assesed via SCID 5
2. Acute depression, assesed via SCID 5
3. Suicidal ideation, assesed via SCID 5
4. Anorexia Nervosa or Bulimia Nervosa
5. Treatment for an eating disorder during the past 6 months

6. Pregnancy
7. Expected absence during treatment period
8. Medication that might 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:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-11-2021
Enrollment:	180
Type:	Actual

Medical products/devices used

Generic name:	Software
Registration:	No

Ethics review

Approved WMO Date:	25-05-2021
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

ID: 24540
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL76368.100.21