Cognitive Behavioral Therapy – Enhanced: A Randomized Controlled Trial comparing online guided self-help to screen-to-screen treatment for Binge Eating Disorder

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It’s hypothesized that both treatments are effective but 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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24540

Bron
NTR

Verkorte titel
TBA

Aandoening

Binge Eating Disorder

Ondersteuning

Primaire sponsor: Arkin, Novarum center for eating disorders
Overige ondersteuning: Arkin, Novarum center for eating disorders

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Cognitive Behavioral Therapy- Enhanced (CBT-E) is an evidence-based 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. 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.

Objective: This study compares the effectiveness 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 effectiveness 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.

Study population: Study population exists of 180 participants diagnosed with Binge Eating Disorder (BED) and Other Specified Feeding or Eating Disorder (OSFED) BED (OSFED BED. All participants were referred to Novarum Center for Eating Disorders by their General Practitioner or other mental health care institutions in order to seek treatment for their eating disorder. Participants are aged ≥ 18 years.
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.

Main study parameters/endpoints: 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 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.

Doel van het onderzoek

It’s hypothesized that both treatments are effective but 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.

Onderzoeksopzet

Amount of objective binge eating episodes will be measured at start, during week 5 of treatment, and at end of treatment (week 20 for screen-to-screen CBT-E and week 12 for guided self-help CBT-E). Follow up measures will be conducted 20 weeks post treatment and 60 weeks post treatment. Due to time differences in end of treatment some measurements will be collected synchronous regarding treatment phase, but asynchronous in time, follow up 20 weeks post treatment (week 32 for guided self-help CBT-E, week 40 for screen-to-screen

CBT-E) and 60 weeks (week 72 for guided self-help CBT-E, week 40 for screen-to-screen CBT-E) after treatment completion.

Onderzoeksproduct en/of interventie

All participants will receive online CBT-E. However, one group will receive guided self-help CBT-E and the other group will receive screen-to-screen CBT-E.

Guided self-help CBT-E

Guided self-help CBT-E is an online version of CBT-E (Fairburn, 2008; Fairburn, Cooper, & Shafran, 2003) Christopher G Fairburn, 1995; C.G.) and is developed by specialists at Novarum Center for Eating Disorders. A software team implemented this into a website and application. During the pilot phase, development on the app was an interactive process involving patients and therapists feedback on user friendliness, ease of navigation lay-out etc. After patients get referred by their GP they have an intitial intake session in order to be assessed. During their advisory session they will be informed about guided self-help CBT-E treatment. Before patients are eligible to start treatment they have to read part one of the book 'Overcoming binge eating' (Christopher G Fairburn, 1995).
guided self-help CBT-E is a 12 week program. Patients have to start to read information online, monitor their eating behavior, schedule weighing once a week and schedule 2 self-evaluation sessions per week. A few days after start of treatment they have a 20 minutes video call session with their therapist. These sessions are pre-scripted in order to ensure consistency between therapists
During the first 4 weeks patients have to monitor their eating behavior, including their thoughts and feelings and establish a regular eating pattern. They also have to introduce alternative activities for binge eating and will work on their problem solving skills. During week five they complete assessment questionnaires and the therapist and patient evaluate the patients progression. Based on this session they decide to add a module on shape concern or dietary restraint during week 6-11 on top of monitoring, regular eating, problem solving and alternatives for binge eating. Before the 12th session patients have to complete the questionnaires. Results are discussed during session 12 and they discuss what to do in order to prevent set-backs.

Therapists are able to activate an account and patients are able to log in in their digital environment through my.karify.com. They have to register with a personal username and password. Patients as well as their therapists are able to access the intervention anytime. Once the patient completes an assignment the therapist receives a notification by email and has the possibility to access the assignments. All therapists are skilled CBT-E therapists, who completed the CBT-E training developed by Centre for Research on Eating Disorders at Oxford (CREDO) (Fairburn, 2008). Therapists have different disciplinary backgrounds and completed a post doc degree (clinical psychologist), masters degree (psychologist) or a bachelors degree (dieticians and social workers). A manual is available for all guided self-help CBT-E therapists. All intervention modules are explained in detail. CBT-E treatment will not be altered or interfered with during the study. Guided self-help CBT-E is a 100% guided self- help treatment without face to face sessions and will not be blended with screen-to-screen CBT-E. Sessions will only be conducted in an online setting. The content of the modules are

presented in appendix A (in Dutch).

Screen-to-screen CBT-E

The other group will Cognitive Behavior Therapy-Enhanced (CBT-E). However, the Covid-19 pandemic requested adaptations to CBT-E (Termorshuizen et al., 2020). As in other specialized centers CBT-E is offered to patients on a screen-to-screen basis (Murphy et al., 2020; Waller et al., 2020). Additional advantage of screen-to-screen CBT-E is increased access for patient's to specialized eating disorder treatment (Abrahamsson et al., 2018). CBT-E is an evidence based psychotherapy for eating disorders. Each session follows a fixed structure, with agenda setting, review of homework, weighing, explanation of rationale of each session, and assignment of homework. Each session has a time frame of 50 minutes, except the first session which lasts 90 minutes. In total 20 sessions will be conducted over 20 weeks. The first four weeks two sessions a week, followed by 10 sessions over 10 weeks and at last three bi-weekly sessions. All therapists are trained CBT-E specialists (Fairburn, 2008). Screen-to-screen CBT-E will not be blended with guided self-help CBT-E during the study,. Screen-to screen CBT-E is a 100% screen-to-screen treatment.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Acute psychosis, assessed via Structural Clinical interview DSM 5 (SCID5)
2. Acute depression, assessed via SCID5
3. Suicidal ideation, assessed via SCID5
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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	180

Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	09-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51181
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9555
CCMO	NL76368.100.21
OMON	NL-OMON51181

Resultaten