Clinical and cost-effectiveness of group schema therapy for complex eating disorders: the GST-EAT study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51433

Source
ToetsingOnline

Brief title
Group schema therapy for eating disorders

Condition

- Other condition

Synonym
Eating disorder; Eating problem

Health condition

eetstoornissen (anorexia nervosa, boulimia nervosa en overige eetstoornissen)

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: CBT-E, Eating disorders, Effectiveness, Group Schema Therapy

Outcome measures

Primary outcome

Main study parameters are eating disorder pathology and incremental cost-effectiveness ration (ICER) after treament. Eating disorder pathology is measured with the Eating Disorder Examination Questionnaire (EDE-Q [13]). This self-report measure is the most commonly used routine outcome measure in ED facilities in the Netherlands to measure the severity of the ED. ICER is assessed by taking into account the annual costs of both treatment and the follow-up effects for both treatments.

Secondary outcome

Secondary study parameters are differences between the CGT-E and GST conditions on quality of life, core cognitions, psychological well-being, clinical perfectionism, and the therapeutic relation.

Study description

Background summary

EDs are a major health care problem that interfere with daily social, physical, and psychological functioning [3], and are associated with high mortality rates [4]. Compared to healthy individuals without EDs, people with EDs have lower

employment participation and higher health-care costs [27]. The World Health Organization estimates that 70 million people worldwide have an ED. Global ED prevalence rates increased from 3.4% to 7.8% between 2000 and 2018 [18], and health care professionals see a *tsunami* of EDs due to the Covid-19 pandemic [34].

Comorbidity has been shown to interfere with ED treatment engagement and effectiveness [20]. Approximately 60% of individuals with EDs also meet a diagnosis for personality disorder, and various personality traits have been found to be associated with ED symptom severity and negative treatment outcomes [30], in particular perfectionism [8]. The majority of research suggests that standard treatments are not consistently effective in addressing personality pathology, such as perfectionism, in EDs [28].

Although several treatments for EDs are described in the *Zorgstandaard Eetstoornissen*, most of these treatments focus on a specific ED (e.g. MANTRA and SSCM for anorexia nervosa, CBT and DGT for bulimia nervosa), while CBT-E is considered a transdiagnostic treatment for all eating disorders. For this reason, CBT-E is often used as the treatment of choice. Although CBT-E has shown positive treatment effects with a 30-50% remission rate, CBT-E is not effective for a significant part of people with an ED [5]. Further, CBT-E shows high drop-out rates (22-50%), especially for anorexia nervosa [15]. During treatment, people with an ED are experts in identifying thinking errors and challenging their own negative thoughts and beliefs, but generally describe very limited changes to their deeply held core beliefs. This is likely related to the fact that CBT-E does not tap into underlying core beliefs nor problems that may originate from childhood experiences such as abuse, neglect or trauma, which are relevant to EDs. The presence of personality pathology in people with EDs who improve on eating symptoms after CBT-E, increases the risk of relapse [32].
For many people, EDs therefore reflect a complex intertwining of behavioural eating pathology and personality pathology. There is a clear need for innovative treatment models that can address ED pathology alongside comorbid personality pathology from a transdiagnostic point of view. The current project aims to overcome the limitations of standard CBT-E treatment for EDs by evaluating the clinical and cost-effectiveness of Group Schema Therapy (GST) for individuals with EDs. Schema Therapy (ST) is an integrative therapeutic approach that is primarily aimed at treating people with entrenched interpersonal and self-identity difficulties [39]. Central to ST are maladaptive schemas and schema modes. Maladaptive schemas refer to a broad, pervasive theme or pattern, comprised of memories, emotions, cognitions, and bodily sensations regarding oneself and one*s relationships with others, which are developed during childhood and elaborated throughout one*s lifetime. Schema modes refer to the moment-to-moment thoughts, feelings, and behaviors of a person when schemas are activated and interact with coping strategies. The main goal of ST is to strengthen the *healthy adult* mode of a person by combining aspects of cognitive, behavioural, psychodynamic, attachment and Gestalt

models. Regulating emotions and behaviors from the healthy adult mode keeps a person within their own window of tolerance. Similar to CBT-E, ST focuses on cognitive and behavioural interventions, yet gives equal weight to emotional needs by means of experiential interventions. For example, imagery rescripting is an experiential interventions used for processing memories of early adverse events, such as childhood abuse and neglect. Furthermore, ST emphasizes the importance of the therapeutic relationship, which is used to provide corrective experiences. GST may therefore buffer against the relatively high drop-out rates of ED patients in standard CBT-E care. ST has proven to be an effective treatment for personality disorders [7], including treatment in a group format [16]. A pilot study of GST for treatment-resistant EDs has yielded promising results [29]. More specifically, a 20-session GST protocol showed a clinically significant improvement in four out of six ED patients and yet unpublished pilot data showed that five out of 12 (41.7%) ED patients that did not improve following CBT-E scored in the healthy range with regard to ED symptomatology after a 26-week GST protocol. Given these promising results, combined with the limited effectiveness of current standardized ED treatments, the present project will strengthen the body of evidence for GST as a treatment for patients that do not benefit from current standard treatments for EDs.

Study objective

The aim of the current project is to test the clinical and cost-effectiveness of GST for patients with an ED (i.e., anorexia nervosa, bulimia nervosa, other specified), that are not likely to benefit from CBT-E. The study will focus on those patients who do not show a clinical response to CBT-E in the first phase (8 sessions) of CBT-E treatment, which is the most robust indicator of poor outcome [2]. GST is a promising yet so far insufficiently tested treatment for patients that do not benefit from current evidence-based and standardized treatments [29]. Specifically, results of our own pilot work showed that patients that were
offered GST after failing to benefit from CBT-E showed a significantly greater improvement in disordered eating behaviours as assessed with the Eating Disorder Examination Questionnaire (EDE-Q) compared to patients continuing in CBT-E, with a medium-large effect size (eta-squared =0.13). In the current project, we build on this encouraging pilot data and will compare the clinical and cost-effectiveness of GST for EDs in a full Randomized Controlled Trial.

Study design

A Randomized Controlled Trial (RCT) with an active control group is used. Patients that fail to show an early response at the end of phase 1 of CBT-E (as measured with the EDE-Q [13]) will be randomized to either a GST arm, or continue with CBT-E as usual. An RCT may provide the strongest empirical evidence for the effects of GST compared to CBT-E.
Figure 1 presents a flow chart of this project providing an overview of the

study design and the different phases. Participants for the project will be recruited at seven eating disorder centers in the Netherlands (GGNet Amarum, Youz Maastricht; MUMC+ Maastricht; GGZ Breburg; GGZ Friesland; Emergis Goes, Accare Groningen/Assen).

Intervention

Investigational treatment - GST
This treatment consists of 26 weekly group sessions of ST for EDs, supplemented with 8 individual ST sessions, and a psycho-education webinar for parents, family members, and/or partners. The individual sessions can be used for imagery rescripting of adverse childhood experiences. The first 5 sessions of the GST focus on explaining the ST model, placing the ED symptoms and behaviours in the context of coping modes, and organizing these in a mode map conceptualization. The following sessions focus on recognising and changing personal coping modes and underlying early maladaptive schema*s, and developing and strengthening the healthy adult mode. GST combines interpersonal, experiential, cognitive and behavioural elements in a unified ST approach [16]. Although not at the core of GST, addressing the physiological aspects of the ED (weight care and (restrictive) eating) is necessary and therefore also incorporated in the protocol.

Active control intervention - CBT-E
This transdiagnostic ED treatment (current standard of care/treatment of choice) consists of 20-40 individual therapy sessions, based on the transdiagnostic CBT model of EDs. CBT-E consists of four phases. In phase one, the patient creates a personal case formulation, and the focus is on psycho-education on maintaining factors and at starting well with monitoring eating behaviours and establishing a regular eating pattern. In phase two, the first phase is evaluated and a treatment plan is made. In phase three, the main mechanisms that are thought to maintain the patient*s ED (over-evaluation of shape, weight, and eating, dietary restraint or restriction, being underweight, and event- or mood-triggered changes in eating behaviour), are targeted, and a relapse plan is created. Phase four focuses on evaluating the progress so far and maintaining the changes that have been obtained [15].

Study burden and risks

Participants will complete a set of questionnaires at the start of treatment phase 1 (pre-measurement) and at the end of this phase (post-measurement), to determine who is eligible for participating in this study. Assessments will also be done at the start of randomisation (T0), at the end of treatment (T1), and 6 (T2) and 12 (T3) months after end of treatment. Participants will complete the questionnaires online through Qualtrics. They can do this after one of the therapy sessions at the treatment center. It will take approximately 120 minutes for completing the set of questionnaires. Completing the

questionnaires may make participants aware of their complaints and problems, which may affect their well-being making them feel a bit inconvenient. However, to the investigators best knowledge, all questionnaires used in this project have been used extensively in previous research with patients causing no risk.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Patients who are in CBT-E treatment at one of the participating ED centers will be eligible for inclusion in the RCT if they fulfil the following inclusion criteria: 1) age > 16 years; 2) A DSM-5 diagnosis of anorexia nervosa, bulimia nervosa, or other specified ED (atypical anorexia nervosa or bulimia nervosa with a low frequency or limited duration; 3) failure to show an early response after phase 1 of CBT-E. Early response to CBT-E is measured with the Eating

Disorder Examination Questionnaire (see outcome measures). The reliable change index will be used to assess whether a patient shows and early response to CBT-E.

Exclusion criteria

Exclusion criteria are 1) not being able to speak and read the Dutch language; 2) being in an acute psychotic mental health state at the start of the study 3) being diagnosed with an autism spectrum disorder 4) having an IQ below 80, as determined with a validated instrument, and 5) showing an early response after phase 1 of CBT-E.

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):	24-07-2023
Enrollment:	230
Type:	Actual

Ethics review

Approved WMO

Date:	22-12-2022
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-06-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-02-2025
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL80491.068.22