Group Schema Focused Therapy for Eating Disorders with Comorbid Personality Disorders

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

Summary

ID

NL-OMON56471

Source
ToetsingOnline

Brief title
STEP

Condition

- Eating disorders and disturbances

Synonym
Eating disorders, Personality disorders

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)
Source(s) of monetary or material Support: intern gefinancierd / opleidingstijd

Intervention

Keyword: Eating disorders, Group therapy, Personality disorders, Schematherapy

Outcome measures

Primary outcome

The main study parameter is change in the severity of ED symptoms in the baseline phase compared to the intervention phase on the one hand and change in the manifestation and severity of dysfunctional core beliefs on the other hand.

This will be measured via:

1. The short form of the Eating Disorder Questionnaire (EDE-QS). This is a 12-item self-report questionnaire with good psychometric qualities (Gideon et al., 2016).

2. The idiosyncratic dysfunctional core beliefs formulated by patients (belief ratings will be expressed on a Visual Analogue Scale (VAS) ranging from 1 - 100).

Secondary outcome

Other parameters of interest in this study are quality of life, psychosocial functioning and the number of patients that drop out. These will be measured through the following instruments:

1. Mental Health Quality of Life Questionnaire (MHQoL). This is a self-report questionnaire with good psychometric qualities.

2. WHO Disability Assessment Schedule 2.0 (WHODAS): 36-item self-report version. This is an assessment instrument measuring problems with psychosocial functioning. It has good psychometric qualities (Üstün et al., 2010).

Study description

Background summary

In the Diagnostic and Statistical Manual of Mental Disorders (5th ed.; DSM-5; (American Psychiatric Association, 2013) Eating Disorders (EDs) are characterized by persisting disturbances in eating habits and over evaluation of weight and shape. There are three subtypes specified in the DSM-5; anorexia nervosa (AN), bulimia nervosa (BN), and binge eating disorder (BED). Additionally, if a patients* symptoms do not meet the full criteria of the three specific ED diagnoses, they can be diagnosed with other specified feeding or eating disorder (OSFED).
The lifetime prevalence differs per subtype. Lifetime prevalences in European women are 1,7-6,3% for AN, <1-6,3% for BN and <1-2,3% for BED (Silén & Keski-Rahkonen, 2022). For males, these rates are 0,3% (AN) to 1% (BN) (van Eeden, 2021). Mortality rates in AN are one of the highest in all psychiatric disorders (5.1%) (van Hoeken & Hoek, 2020).
Rigid personality traits are common within the ED population. Personality disorders (PDs) are highly comorbid in EDs, with the highest proportion of cluster C PDs in AN, and cluster B PDs for BN (Cassin & von Ranson, 2005; Martinussen et al., 2017). According to the cohort study of Momen et al., there was a relative risk of 4.5 for people with AN for comorbid personality disorder (Momen, 2022). For people with other eating disorders this risk was 5.1. In a meta-analysis conducted by Cassin & von Ranson (2005), perfectionism, obsessive-compulsiveness, neuroticism, negative emotionality, harm avoidance, low self-directedness, low cooperativeness, and traits associated with avoidant PD were found in patients with AN or BN. AN (restrictive type) was found to be more strongly associated with low novelty seeking, high constraint and persistence, where BN was found to be more associated with high impulsivity and sensation seeking. Personality traits in BED and AN (purging type), suggest similarities to BN (Cassin & von Ranson, 2005). Comorbid PD has been shown to adversely affect treatment outcomes (Farstad et al., 2016; Grilo, 2007). In research on the natural course of eating disorders (Grilo et al., 2007); no differences in rate of remission or relapse where found depending on a PD diagnosis, except for avoidant PD among patients with EDNOS.
According to the Dutch standard of care, Cognitive Behavioural Therapy-enhanced (CBT-e) is treatment of first choice for people with EDs, where AN follows an extended version of the standard protocol used for BN and BED (AkwaGGZ, 2017). CBT-e has been shown effective in a broad range of patients (de Jong, 2016; Fairburn, 2009; Murphy et al., 2010), where CBT-Eb (which targets major clinical problems such as mood intolerance, clinical perfectionism and low self-esteem next to eating disorder features) was proven to be more effective in those with more complex psychopathology (Fairburn, 2009).
Findings suggest high drop-out rates for treatment in patients with EDs (S.

Fassino, 2009). In his review he concluded that patients with more impulsivity and/or emotional dysregulation are generally more at risk for dropout during treatment. These patients also seem to have a genetic predisposition to psychiatric and personality comorbidity and poorer treatment outcomes.
Although CBT-e is an effective treatment for EDs, a significant proportion of patients does not respond well to CBT. It has been suggested that the cognitive models do not sufficiently account for the roles of past experiences and core (self)beliefs on eating disorder development and maintenance (Schmidt, 2007). A therapy that does account for these factors, via so-called early maladaptive schema*s (EMS), is Schema Focused Therapy (SFT). It was originally introduced by Young as a response to the high dropout rates of patients with personality disorders. The theory integrates elements of CBT frameworks and other psychotherapeutical schools. Central in his theory are the EMS, defined as implicit beliefs about the self and the relationship with the environment (Young, 1990).
Research has shown that schema therapy is a promising intervention for complex eating disorders (Pugh, 2015). It has been shown that ED patients have more EMS than healthy controls, with no significant differences between the clinical ED subgroups (Dingemans, 2006). Prelimenary research conducted by Simpson showed important clinical improvements on both eating disordered symptoms as well as severity of EMS and quality of life. Although this was a pilot study, it showed that ED patients can benefit from SFT in a group setting (Simpson et al., 2010). Our goal is to further investigate this effect. In this study a multiple baseline case series design will be used.

Study objective

The primary objective of the study is to examine the effects of group SFT for an out-patient ED population, as assessed by change in both ED pathology as in core self-beliefs.

Hypotheses:
1. There will be a decrease in dysfunctional core self-beliefs over time
2. There will be a decrease in ED symptoms

The secondary aim of this study is to examine the effect of group SFT for ED on secondary clinical outcomes, namely self-reported general functioning.

3. There will be an increase of Quality of Life and psychosocial functioning

Study design

The proposed design is a multiple baseline case series, with a baseline varying in length from 5 to 9 weeks, with 12 participants randomly allocated to each of the 3 lengths (4 patients per condition). This design is proposed as an alternative to the randomized control trial, because fewer participants are

required to establish an intervention effect.
The variation in baseline length offers the possibility to differentiate between time effects and experimental effects of the treatment. After baseline, a 30 week treatment phase follows, during which the group SFT protocol will be applied. There will be 30 weekly measurements during the intervention phase, plus 4 additional moments / periods of assessment: start of baseline, during the pre-treatment baseline phase (5-9 weekly measurements), post-treatment (5-9 weekly measurements: frequency inversely related to those during the baseline phase) and at follow-up (1 measurement: 3 months after completing the intervention).

Intervention

Thirty weekly sessions of 90 minutes of group SFT will be offered to participating patients. The therapy will be based upon the protocol described by Tjoa & Muste (2021), which in its turn is based on the schema therapy model of Farrell & Shaw (2012, 2014).
Participating therapists are licensed psychologists, psychotherapists or clinical psychologists that have undergone basic training in schema therapy.

Study burden and risks

Not applicable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- A co-morbid ED and PD diagnosis according to DSM-5
- Previous ED-treatment had not been sufficient in diminishing the symptoms of ED
- Age 18-65
- Dutch as a first language (or estimated as sufficient to receive treatment in Dutch)
- Willingness to participate in the study (signed informed consent)

Exclusion criteria

Current PD treatment

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2024
Enrollment:	12

Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	21-02-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL84203.018.23