Autonomy-enhancing therapy for eating disorders

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Primary Objective: To assess AET*s effectiveness concerning eating disorder symptoms, autonomy-connectedness (primary outcome measures), general psychopathology, self-esteem and quality of life (secondary outcome measures). Secondary Objective(s):...

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

Summary

ID

NL-OMON53339

Source
ToetsingOnline

Brief title
AET and ED

Condition

- Eating disorders and disturbances

Synonym
Anorexia Nervosa, Boulimia Nervosa, Eating disorder

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Oost Brabant (Rosmalen)
Source(s) of monetary or material Support: GGZ Oost-Brabant

Intervention

Keyword: Autonomy-connectedness, Autonomy-enhancing therapy, Eating Disorders

Outcome measures

Primary outcome

Multiple Baseline Design

The Eating Disorder Examination Questionnaire - Short (Gideon et al., 2016) is a brief, reliable and valid measure of eating disorder symptom severity. It consists of 12 items and was developed for routine, including session-by-session and outcome assessment. Gideon et al. found that it performs similarly to the EDE-Q lending itself for the use of sessional outcome monitoring in treatment and research (2016).

The Autonomy-Connectedness Scale (revised) (ACS-30) is an amended version of the Autonomy-Connectedness measure, the ACS-30 (Bekker & van Assen, 2006). As the ACS-30 does not allow for measuring short-term changes, we adapted it to the ACS-30-S. The ACS-30-S instruction asks about participants* experiences during the past week (instead of *Usually*, as in the original ACS-30).

Existing questions have been rephrased where timing is concerned (e.g. *I often long for** has been changed to *I have longed for**).

The ACS-30-S has been reviewed by a convenience sample to assess acceptability and feasibility, after which a few changes were made, concerning questions that were hard to answer on a weekly basis (e.g. *When making important decisions about my life, I leave other peoples* opinions and wishes out of consideration* was changed to *When making decisions I leave other peoples* opinions and

wishes out of consideration*.) This process was repeated until the questionnaire was easy to use. Psychometric properties of the ACS-30-S will be conducted in the course of this study.)

Repeated Measures design

The Autonomy-Connectedness Scale (ACS-30) (Bekker & van Assen, 2006) consists of 30 items and three subscales: Self-awareness, Sensitivity to others, and Capacity for managing new situations. All items are measured on a 5-point Likert scale, running from 1 (disagree) to 5 (agree). The ACS-30 has been shown to have good psychometric properties. Norm scores are available and, agreeing with ACs gender-sensitivity, separate SO norm scores exist for both sexes.
The EDE-Q (Luce & Crowther, 1999) assesses eating disorder pathology. It measures four eating attitudes during the previous 28 days, using four subscales: Restraint, Eating Concerns, Shape Concerns and Weight Concerns. The scale consists of 36 items and has shown excellent internal consistency and test-retest reliability.

Secondary outcome

The SCL-90 (Derogatis, 1994) consists of 90 items and 8 subscales. Norm scores are available for the general population and psychiatric patients. The reliability and validity of the SCL-90 are reported to be good.
Self-esteem is measured with the RSES (Sinclair et al., 2010), which consists of 10 items and assesses global self-esteem. All items, containing positive and negative statements about the self, are rated on a 4-point Likert scale ranging

from *strongly agree* to *strongly disagree*. The reliability and validity of the RSES are reported to be good (Schmitt & Allik, 2005).

Quality of life is measured with the WHOQOL-BREF (The Whoqol Group, 1998), which consists of 26 items, including four Quality of life domains: physical health, psychological health, social relationships and environment. Additionally, two items examine general Quality of life. All items are rated on a 5-point Likert scale with 0 meaning *not at all*, *never*, *very poor*, or *very dissatisfied*, and 4 meaning *completely*, *always*, *very good*, or *very satisfied*. Psychometric properties have been studied in psychiatric outpatients and are reported to be good (Trompenaars et al., 2005)

Study description

Background summary

Eating disorders are among the most serious but least successfully treated mental disorders. In fact, to date, no evidence-based treatment for adults with Anorexia Nervosa (AN) exist. Global eating disorder prevalence increased from 3.4% to 7.8% between 2000 and 2018, and there are reports of further increasing rates worldwide (Galmiche et al., 2019). Due to COVID-19, child and adolescent eating disorder services have seen almost a doubling in the number of urgent and routine referrals, making eating disorders the fifth most prominent mental health condition by August 2020 (FAIR health, 2021).

Eating disorders are associated with great functional impairment, morbidity and mortality, with AN having the highest mortality rate of any psychiatric disorder (Arcelus et al., 2011). At present, only approximately 50% of patients recover after treatment (Hay et al., 2014) and even after successful treatment, relapse is high, ranging from 22% to 51%.

Because of the major role of transdiagnostic factors in causing and keeping eating disorders (Connan et al., 2003; Fairburn et al., 2003; Treasure et al., 2012), we propose to investigate the innovative and gender-sensitive Autonomy-Enhancing Treatment (AET). AET focuses on underlying transdiagnostic autonomy deficits. Autonomy deficits characterise many psychiatric disorders,

including eating disorders (Bachrach et al., 2013; Bekker et al., 2007; Bekker & Belt, 2006; Bekker & Croon, 2010; van Assen & Bekker, 2009), and are reflected by a strong focus on the needs and wishes of others and a poor ability to acknowledge and communicate one's own needs. AET has recently been established as a(n) (cost-)effective treatment for anxiety disorders (Kunst et al., 2022), and autonomy was one of the strongest predictors of recovery from eating disorders in previous research (Kuipers et al., 2017).

Currently, AET is already implemented in the final phase of treatment at our Centre for Eating Disorders (GGZ Oost-Brabant, Helmond). Patients enter the final phase of treatment when the eating disorder is under control on a behavioural level. It is based on further stabilisation, re-integration, and relapse prevention. AET seems to fit very well in this phase of treatment, as in this stage, patients struggle with who they are without the eating disorder. They start learning more about their identity, become aware of, and act on boundaries, needs and emotions, and learn to prioritise themselves instead of only others in relationships. Practice-based evidence shows that patients value this person-centred approach, as they feel AET penetrates the core of their psychological problems. Given the alarming rise of ED prevalence, the current lack of evidence-based treatment for adults with anorexia nervosa, and the promising results for the effectiveness of AET for, e.g., anxiety disorders, the natural next step is to investigate AET*s effectiveness for eating disorders.

Study objective

Primary Objective: To assess AET*s effectiveness concerning eating disorder symptoms, autonomy-connectedness (primary outcome measures), general psychopathology, self-esteem and quality of life (secondary outcome measures).

Secondary Objective(s): To investigate if autonomy will mediate the decrease in eating disorder symptoms.

Study design

We propose a multiple baseline design to investigate the effectiveness of AET in the final phase of multidisciplinary treatment. Participants will be patients at the GGZ Oost Brabant multidisciplinary centre from the AN and BN group (this group is combined, for further details on treatment infrastructure and context, see below) in the final phase of treatment.
A multiple baseline design will be used, with short-term eating disorder symptoms and short-term autonomy connectedness as primary parameters. Additionally, a repeated measures design will be used with long-term eating disorder symptoms and long-term autonomy connectedness as primary parameters and quality of life, self-esteem, depression and anxiety as secondary parameters.

Intervention

Baseline consists of 5 to 13 weeks of treatment as usual in stage two of treatment.

The investigational treatment, AET, consists of weekly 2-hour sessions following the AET-protocol (Bekker et al., 2016). AET groups have an average of 8 participating patients (range 4-9). Sessions consist of psycho-education about autonomy-connectedness, its relation to eating disorders and setting autonomy-related personal goals. Each group member, supported by the therapists, also acts as chairperson once, which entails keeping time and structuring the group discussion to practice assertiveness. Sessions feature different autonomy-related themes each week, serving as psycho-education as well as grounds for discussion about autonomy-related difficulties (e.g. relationships, boundaries, body and sexuality, emotions). The goal of the treatment is to enhance understanding, feelings and behaviours of autonomy by working on personal, autonomy-related goals.

Study burden and risks

Patients who participate in this study receive treatment offered in a centre with expertise in treating eating disorders. The only difference between taking part and not taking part in the study is the filling out of questionnaires. On a weekly basis, this is expected to take less than fifteen minutes, and will be done within sessions. On a three-monthly basis, this is expected to take +- 30 minutes.

AET is part of standard treatment. We do not anticipate any risks to patients through participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Being in the final phase of treatment at the Multidisciplinary Center of Eating disorders after completing the AN or BN daycare treatment track.

Exclusion criteria

Patients who have not given informed consent to use their data for scientific purposes.
No patients with a BMI lower than 15 are found in the final stage of treatment, excluding them naturally from this study as well.
No patients younger than 18 years old are found in the final stage of treatment, excluding them naturally from this study as well.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2023
Enrollment:	36
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-06-2023
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	NL83503.018.23