A feasibility study of an adjunctive dissonance-based treatment intervention for eating disorders

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Primary Objective: a) piloting the intervention- to identify whether DBI is feasible and acceptable (tolerability, appropriateness, usefulness) being studied from both the perspective of study participants, the research team and clinicians, and...

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

Summary

ID

NL-OMON45364

Source
ToetsingOnline

Brief title
Dissonance based treatment intervention for eating disorders

Condition

- Eating disorders and disturbances

Synonym
anorexia/bulimia nervosa, eating disorders

Research involving
Human

Sponsors and support

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

Intervention

Keyword: acceptability, dissonance based treatment intervention, eating disorders, feasibility

Outcome measures

Primary outcome

Qualitative and quantitative assessment of acceptability, satisfaction, and

feasibility collected from participants, clinicians and the research team,

focusing on the intervention and on the conduct of the trial.

Secondary outcome

Changes in self-objectification, thin-ideal internalization, body

dissatisfaction, eating disorder pathology, and depressive and anxiety

symptomatology.

Study description

Background summary

Eating disorders are difficult to treat; even after successful treatment relapse is a significant problem with rates ranging from 22% to 51% across outcome studies of anorexia and bulimia nervosa (Eckert, 1995; Herzog, 1999; Keel, 2005). As a result, efforts have been devoted to development of interventions that can prevent the onset of eating disorders. Dissonance based (prevention) intervention has received the greatest amount of empirical support (DBI; Stice, Shaw, Becker, & Rohde, 2008). DBI identifies body dissatisfaction as one of the leading risk and maintenance factors of eating disorders. Indeed, body dissatisfaction is a key diagnostic feature of anorexia nervosa and bulimia nervosa, and continued body dissatisfaction is found to be a major predictor of relapse in patients treated for anorexia nervosa and bulimia nervosa (Keel, 2005). Thus, to improve outcomes in the treatment of eating disorders, adjunctive strategies are needed that target body dissatisfaction.

DBI makes use of cognitive dissonance to address thin-ideal internalization, body dissatisfaction, and eating disorder symptoms. The theory of cognitive dissonance proposes that when there is an inconsistency between an individual*s

beliefs and behaviours, the resulting discomfort will motivate them to change their attitude or behaviours to reduce this inconsistency (Festinger, 1957). More specifically, in DBI women with body image concerns voluntarily and actively engage in verbal, written and behavioural exercises in which they challenge beliefs about the thin-ideal.

A great deal of evidence supports DBI as an effective preventive treatment (Becker, Smith, & Ciao, 2005; Green, Scott, Diyankova, Gassner, & Pederson, 2005; Matusek, Wendt & Wiseman, 2004; Mitchell, Mazzeo, Rausch, & Cooke, 2007; Roehrig, Thompson, Brannick, & van den Berg, 2006; Stice, Chase, Stormer, & Appel, 2001). Moreover, Stice, Rohde, Butryn, Menke, and Marti (2015) found preliminary support for the use of modified DBI as a stand-alone group treatment for people already diagnosed with an eating disorder.

Evidence for DBI for full-blown eating disorders is still preliminary and has not focused on a treatment-seeking population with more severe and therefore also possibly a different type of eating disorder pathology. Given the heterogeneity of the patient group and the complexity of the typically comprehensive treatment and infrastructure within and across eating disorders centers, the goal of the currently proposed study is not only to investigate preliminary effectiveness of the intervention, but also to test the feasibility and acceptability of DBI.

The two primary objectives of the proposed study are therefore to identify whether DBI is feasible and acceptable (tolerability, appropriateness, usefulness) being studied from both the perspective of study participants, the research team, and clinicians, to determine any necessary modifications, and to test procedures for a future RCT. Additionally, patients will complete standardized questionnaires to preliminary investigate effectiveness of DBI, which comprises the secondary objective of the currently proposed study.

Study objective

Primary Objective: a) piloting the intervention- to identify whether DBI is feasible and acceptable (tolerability, appropriateness, usefulness) being studied from both the perspective of study participants, the research team and clinicians, and determine any necessary modifications; b) piloting the trial processes- to test procedures for a future pilot/ definitive RCT, especially in relation to eligibility criteria, recruitment and retention rates.

Secondary Objective(s): preliminary testing the effectiveness of DB I- to systematically assess changes in all variables that appear in the models of self-objectification theory and the dual pathway model - self-objectification, thin-ideal internalization, body dissatisfaction, negative affect and eating disorder pathology. Analyses regarding effectiveness will be exploratory.

Study design

Randomized pilot controlled study comparing dissonance based intervention to psycho-education, both in addition to TAU.

Intervention

Patients are randomized to either receive dissonance based intervention or psycho-education, both in addition to TAU.

Study burden and risks

There are no evident risks involved for participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients diagnosed with Anorexia Nervosa, Bulimia Nervosa and EDNOS (BED excluded)

Exclusion criteria

Male, BED, schizophrenia or other psychotic disorders, substance abuse

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:	Recruitment stopped
Start date (anticipated):	16-11-2017
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO

Date:	27-06-2017
Application type:	First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL60165.091.17