

# Processes and Outcomes of Cognitive Therapy vs. Cognitive Therapy + Exposure for Eating Disorders: Study protocol for a Randomized Controlled Trial

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27127

### Source

Nationaal Trial Register

### Brief title

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### Health condition

Eating Disorders; Bulimia Nervosa; Eating Disorder Not Otherwise Specified / Eetstoornissen; Boulimia Nervosa; Eetstoornis niet anderszins omschreven.

## Sponsors and support

**Primary sponsor:** Maastricht University

**Source(s) of monetary or material Support:** Maastricht University

## Intervention

## Outcome measures

### Primary outcome

Severity of specific Eating Disorder pathology (including body satisfaction/esteem); Meeting/not meeting DSM criteria for any of the Eating Disorders.

### Secondary outcome

Craving; Self-control; Impulsivity; Irrational thinking; Attention bias for negatively perceived body parts and high caloric food; Personality problems/disorders; Self-esteem; Mood; General well-being/psychopathology; Body Mass Index (BMI) and Various potential (treatment specific / non-specific) process measures

## Study description

### Background summary

Cognitive Behavioural Therapy (CBT) has shown to be an effective treatment for various Eating Disorders. However, since approximately 30% of patients do not (or insufficiently) respond to treatment there is room for improvement. When taking a closer look at the protocols that are currently being used in clinical practice, it can be concluded that existing protocols often have a relatively strong focus on diet management. More emphasis on the cognitive aspects of CBT might make treatment more effective. Furthermore, there are indications that specific exposure elements (e.g. cue exposure, forbidden foods exposure, and positive body exposure) might be effective as well. Combining cognitive interventions with these exposure exercises might therefore also increase treatment effects. These ideas were leading ground for designing the current RCT. In this study, 106 adults with an Eating Disorder (BN, BED, and ED NOS) will receive psychotherapy (CT or CT + Exposure) in an outpatient mental health clinic in the Netherlands. Treatment consists of 20 individual sessions of 60 minutes (3 pre-sessions, 16 treatment sessions, 1 booster session). Primary outcome is severity of eating disorder pathology. Secondary outcomes include self-esteem, body satisfaction, mood, general psychological distress, craving, impulsivity and BMI. In addition, measures of various potential mechanisms of change are included. Assessments are taken at baseline, pre- and post-treatment, prior to-, during- and after each therapy session, and at 1, 6, 12 and 24 months follow-up. By including repeated measures of clinical outcomes and multiple potential process measures over the course of 2.5 years, we aim to examine both the clinical effects (acute and long-term) of both interventions, as well as the causal pathways that lead to therapeutic change.

### Study objective

CT + (Cue) Exposure is more effective than Pure CT (both in short- and long-term).

## Study design

Intake; pre- and post-treatment; prior to-, during- and after each therapy session; and at 1, 6, 12 and 24 months follow-up.

## Intervention

Cognitive Therapy  
Cognitive Therapy + (Cue) Exposure

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

Adults with Eating Disorders BN/ED-NOS as primary diagnosis.

### Exclusion criteria

BMI < 18; primary diagnosis other than ED; elevated acute suicide risk, concomitant psychological treatment; drugs and alcohol abuse/dependence; insufficient knowledge of the

Dutch language; mental retardation (IQ < 80).

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2009
Enrollment:	106
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	09-08-2017
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 44125  
Bron: ToetsingOnline  
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL6420
NTR-old	NTR6597
CCMO	NL17291.068.07
OMON	NL-OMON44125

## Study results

### Summary results

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