

# Treatment study concerning the influence of self-regulation on undesirable eating behaviour (binging) among people with boulimia nervosa or binge eating disorder.

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

## Summary

### ID

NL-OMON55658

### Source

ToetsingOnline

### Brief title

Study on the influence of self-regulation on undesirable eating behaviour

### Condition

- Eating disorders and disturbances

### Synonym

Boulimia nervosa and Binge eating disorder; binge eating

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Binge Eating Disorder, Boulimia Nervosa, Eating Disorders, Implementation Intentions

## Outcome measures

### Primary outcome

The ultimate goal is to reduce the number of binges. This is measured by (1) the foodintake diary, which specifically requests binge eating, (2) the Eating Disorder Examination Questionnaire (EDE-Q; Fairburn & Beglin, 1994) and (3) the Eating Disorder Inventory-II (EDI II ; Garner & Van Strien, 2002).

### Secondary outcome

A secondary study parameter is negative affect. This will be measured by the Positive and Negative Affect Schedule (PANAS; Watson, Clark & Tellegen, 1988).

## Study description

### Background summary

Bulimia Nervosa (BN) and Binge Eating Disorder (BED) are both characterized by recurrent binge eating (American Psychiatric Association, 2013). In up to two hours an unusually large amount of food is eaten accompanied by loss of control. Implementation intentions (IIs) could be a good intervention because they rely on the automatic components of self-regulation (Mobbs, Crépin, Thiéry, Golay & Van der Linden, 2010). IIs are 'if-then plans' linking behavior with contextual features to control subsequent behavior (Gollwitzer & Brandstätter, 1997), for example, "If situation X occurs, then I react with response Y!". IIs are therefore used in order to achieve a (long-term) goal. IIs could be helpful for people who suffer from eating disorders, in achieving their goal of having no more binges.

## **Study objective**

The objective of the study is to develop a treatment aimed at the reduction of binge eating in people with BN or BED which can act as a supplement to the regular treatment (CGT).

The primary objective of this study is to investigate whether a IIs-treatment in people with BN or BED leads to a reduction in the number of binges and negative affect.

Secondary, we examine whether IIs focused on the negative affect that often precedes a binge (emotion regulation-IIs) are more effective than IIs focused directly on the binge itself (behavioral regulation-IIs).

## **Study design**

The study is a randomized, controlled, single blind intervention study.

## **Intervention**

Participants are randomly divided into three groups. The first (experimental) group will be receiving a treatment with behavioral regulation-IIs focused directly on the binge itself. The second (experimental) group will be receiving a treatment with emotion regulation-IIs focused on the negative affect that often precedes a binge. IIs are not offered to the third (control) group; they only form goal intentions. In each group there are three individual weekly treatment sessions, during three weeks.

## **Study burden and risks**

There will be two online pre-measurements, three treatment sessions during three weeks, one online post-measurement and three follow-up measurements, respectively, 1 month, 3 months and 6 months after the post-measurement. In addition, a food diary is daily maintained in the period in which the treatments take place.

There are no risks associated with participation in this study.

## **Contacts**

### **Public**

Universiteit Maastricht

Universiteitssingel 40

Maastricht 6200 MD

NL

### **Scientific**

Universiteit Maastricht

Universiteitssingel 40  
Maastricht 6200 MD  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

- Bulimia Nervosa or Binge Eating Disorder diagnosed according to the DSM-V criteria.
- age: 18 years or older

### Exclusion criteria

- Anorexia Nervosa diagnosed according to the DSM-V criteria.
- BMI < 18.5
- Age < 18
- Dependency on substances
- Unable to communicate in Dutch

## Study design

### Design

Study type: Interventional

Intervention model: Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2016
Enrollment:	105
Type:	Actual

## Ethics review

Approved WMO	
Date:	16-09-2015
Application type:	First submission
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	NL52600.068.15