

# An experience sampling method (ESM) app for the treatment of binge eating disorder: A proof-of-concept study

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1) We examine whether individuals who binge eat, and their mental health care professionals value the ESM app as a useful tool in BED treatment; 2) We examine which emotional and situational factors and fluctuations of these factors immediately...

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|------------------------------|-----------------------------------|
| <b>Ethical review</b>        | Approved WMO                      |
| <b>Status</b>                | Recruiting                        |
| <b>Health condition type</b> | Eating disorders and disturbances |
| <b>Study type</b>            | Interventional                    |

## Summary

### ID

NL-OMON52344

### Source

ToetsingOnline

### Brief title

ESM app for binge eating disorder treatment

### Condition

- Eating disorders and disturbances

### Synonym

binge eating, binge eating disorder

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Erasmus Universiteit Rotterdam

**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** Binge eating disorder, Ecological momentary assessment, Experience sampling, Treatment

## Outcome measures

### Primary outcome

Aim 1: Qualitative evaluations of the practical use and added value of the app for treatment. Aim 2: Within-person mean-level changes in emotions and situations and its bi-directional associations with binge eating episodes and cravings will be examined with the data collected with the ESM application.

### Secondary outcome

Not applicable.

## Study description

### Background summary

Binge eating disorder (BED) is the most common eating disorder. It has a detrimental effect on individual's health and well-being, as it may lead to obesity, depressive symptoms and substance abuse. Research using the Experience Sampling Method (ESM) which assesses daily emotions and activities suggests that mood changes precede binge eating episodes among BED patients. Such fine-grained information about modifiable behaviours and emotions can be used to detect individualized treatment targets.

### Study objective

- 1) We examine whether individuals who binge eat, and their mental health care professionals value the ESM app as a useful tool in BED treatment;
- 2) We examine which emotional and situational factors and fluctuations of these factors immediately precede and follow binge eating episodes and cravings.

### Study design

Longitudinal intervention study, with 6 weeks of Experience Sampling (ESM) integrated within a smartphone app. After 6 weeks, a qualitative,

semi-structured interview evaluates the practical use and added value of the app.

## **Intervention**

ESM app as an additional tool to TAU:

In the first week of treatment, participants are asked to download the app on their phone and to start the monitoring. They receive 5 semi-random notifications per day on their smartphone as an invite to fill out micro-questionnaires. If a participant does not fill in the micro-questionnaire, s/he will receive a notification after 30 minutes to remind the participant to fill out the questionnaire.

Participants are also instructed to initiate an ESM report during a binge eating episode, right after a binge eating episode or when they experience a strong urge to binge eat. The reports of each participant are automatically included in the personal graph in their app, which monitors daily fluctuations in emotions and the occurrence of binge eating events. The participants can evaluate their emotions and binge eating episodes in the graph any time and can select the emotions of interest.

In the first 6 weeks of treatment, the therapist briefly discusses the graph with the participants during each group treatment session. All assessments of micro-questionnaires are included in the graph and may offer participants insight in their pattern of binges and its triggers.

## **Study burden and risks**

Data collection takes 6 weeks\* time, during which participants receive semi-random beeps on their smartphone at 5 random times during the day as an invite to fill out 5 micro-questionnaires. Per beep, it takes a 1-2 minutes to fill out the micro-questionnaire. Pilot studies with the app in the general population indicated that the burden is minimal. In fact, as we want to offer participants a tool to support them in overcoming their binge eating episodes, we expect that participants will be motivated to use the app. The app prototype has already been used by lead investigator Jansen in the Generation R Study, and will be approved by the privacy and security office of the Erasmus University Rotterdam. Collected data will be stored on a secured server.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

In order to be eligible to participate in this study, a subject must meet be an adult aged 18 to 65 years old, known to have binge eating disorder according to the DSM 5 classification and who are indicated to be treated with group therapy.

### Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

1. Inability to understand Dutch, inability to read or write Dutch
2. No internet access or no email or no cell phone.
3. Patients who do not fill out their baseline questionnaires
4. People who use medication that is known to trigger binges, such as corticosteroids, antipsychotics and some antidepressants (e.g. mirtazapine) or antihistamines (e.g. promethazine).
5. People who are suspected to have a monogenetic pathology as the cause of their obesity and binges.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 03-08-2021

Enrollment: 20

Type: Actual

## Ethics review

Approved WMO

Date: 26-07-2021

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 09-06-2022

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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     | NL75943.078.20 |