Beating the Binge

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26203

Source
Nationaal Trial Register

Brief title
BtB

Health condition

Eating Disorders; Binge Eating.

Sponsors and support

Primary sponsor: NWO VENI grant (451-17-022) Maastricht University, Department of Psychology and Neuroscience
Source(s) of monetary or material Support: NWO VENI grant (451-17-022)

Intervention

Outcome measures

Primary outcome

Frequency and severity of binge eating episodes.

Secondary outcome

Density and centrality of networks related to binge eating; Believability of dysfunctional cognitions; Severity of specific eating disorder pathology (including body

satisfaction/esteem); Meeting/not meeting DSM criteria for any of the Eating Disorders; Craving; Irrational thinking; Self-control; Impulsivity; Self-esteem; Mood; General well-being/psychopathology, General psychological functioning, social functioning and quality of life; Body Mass Index (BMI); and various potential (CBT specific and non-specific) process measures.

Study description

Background summary

Binge eating, the uncontrolled consumption of large amounts of food in a short timeframe, is a common and severe phenomenon with many negative consequences. Existing treatments for binge eating are promising, but with short- and long-term remission rates ranging from 37-69%, there is substantial room for improvement. As a starting point for treatment improvement, insight in the mechanisms that drive binge eating is crucial. The leading theoretical explanation for the occurrence of binge eating resides in cognitive-behavioural theory. According to this theory, dysfunctional beliefs about e.g., (the function of) eating, weight and body shape play a decisive causal role in the complex network of environmental, psychological, physiological, and behavioural factors that drive binge eating. Unfortunately, comprehensive empirical evidence for the cognitive-behavioural explanation of binge eating is lacking. As a result, it remains to be tested whether cognitions actually do play a crucial role in binge eating, or whether binge eating can be better predicted by other factors.

This project will take the understanding of binge eating a critical step further by using an innovative approach to systematically study the predictors of binge eating – and the role of cognitions in particular – in real time using Ecological Momentary Assessment (EMA). Subsequently, this information will be used this information to develop and test (RCT) a personalised tool (ecological momentary intervention: EMI) for preventing binge eating in daily life. With this, the project might bridge the gap between the therapist’s office and daily life.

The RCT is based on two preparatory studies. In study 1 cognitions associated with binge eating will be explored and categorised. 120 individuals with binge eating episodes will be recruited from the community. Participants are asked to monitor eating behaviour for a 2-week period. Consistent with other research in the field, participants will make reports before and after each eating moment. Before eating, the type of eating moment (breakfast, lunch, dinner, other), level of craving and restraint, emotional state, and cognition(s) about eating are reported. After eating, the type and quantity of food consumed, and level of control is assessed. Data will be collected through a smartphone app. A classification algorithm will distinguish binge eating episodes from other eating moments. Cognitions will be categorised and serve as important input for study 2 and for the RCT. It is hypothesised that binge eating episodes are preceded by dysfunctional cognitions related to the following categories: 1) eating, shape and weight concerns; 2) stress related cognitions; 3) positive beliefs about (the function of) food; 4) thoughts of having no control.

In study 2 (n = 120), all factors of the cognitive-behavioural model will be assessed repeatedly and in real-time using EMA. Network Analyses will be conducted to examine their longitudinal connections and relative impact on binge eating. The duration and procedure for monitoring eating behaviour is similar to study 1, although now categories of cognitions are presented. Furthermore, information about activities and company is obtained. In addition to registration of eating moments (event-contingent recordings), similar input will be requested at several pseudo-random moments throughout the day (signal-contingent samples). This allows further examination of time-lagged associations. Furthermore, sensor data (e.g., sleep, activity level, heart rate) will be collected continuously via a smartwatch. Similar to study 1, a decision tree algorithm will distinguish binge eating episodes from other eating moments. Time-lagged multilevel network analyses will be conducted to examine connectivity between variables and to study their (relative) effects on eating behaviour. It is hypothesised that dysfunctional cognitions play a central role in the complex network of psychological, environmental, physiological, and behavioural factors that drive binge eating.

This information will then be used to design and test (RCT) a new personalised real-time EMI aimed at targeting the key concepts of binge eating using principles of cognitive-behavioural therapy (CBT) The EMI will use EMA data to predict person-specific binge eating behaviour and alerts individuals when at risk. When warned, or at any desired moment, individuals have access to tailored CBT techniques to help them.

RCT
148 individuals with binge eating episodes are randomly allocated to either an active condition (monitoring + 6-week CBT-based EMI intervention) or a monitoring-only control condition (followed by the intervention). Since EMI uses EMA data to predict binge eating, participants will provide daily EMA data throughout the intervention phase (procedure similar to study 2). In the active condition, the app will use this information to predict binge eating episodes and to provide appropriate in-the-moment treatment. Basic CBT skills are acquired via an online training (variation of a training previously developed by the applicant). The main outcome is frequency and severity of binge eating episodes. Secondary outcomes include believability of dysfunctional cognitions, severity of specific eating disorder pathology (including body satisfaction/esteem); Craving; Self-control; Impulsivity; Irrational thinking; Self-esteem; Mood; General well-being/psychopathology, Body Mass Index (BMI) and density and centrality of networks related to binge eating. Outcomes are assessed at baseline (T1), weekly during the intervention (T2-T5), at post-treatment (T6), and at 1 and 3 months follow-up (T7-T8; see Figure 3). EMA data will be collected daily from T1 to T6 (week 1-8). For EMA data, time lagged-multilevel network analyses will be conducted to assess pre- to post-intervention changes in connectivity, density and centrality of networks related to binge eating. For questionnaire data, 2x2 ANOVA’s will be conducted.

Study objective

Compared to monitoring-only, a personalised CBT-based EMI aimed at targeting key constructs of binge eating will lead to stronger reductions in a) the frequency of binge eating, b) the believability of dysfunctional cognitions, and c) the connectivity and density of networks related to binge eating, and to stronger changes (in expected/healthy directions) on other secondary outcomes (see further).

Study design

EMA data: daily from T1 to T6 (week 1-8).
Questionnaire data: baseline (T1), weekly during the intervention (T2-T5), at post-treatment (T6), and at 1- and 3-months follow-up (T7-T8).

Intervention

Active condition (monitoring + 6-week CBT-based EMI intervention) vs. Monitoring-only control condition (followed by the intervention).

Contacts

Public
Maastricht University
Lotte Lemmens

+31433881874
Scientific
Maastricht University
Lotte Lemmens

+31433881874

Eligibility criteria

Inclusion criteria

Age between 18-65; in possession of a smartphone; recurrent objective binge eating episodes (at least once a week during the past four weeks); BMI > 18.5.

Exclusion criteria

Pregnancy, severe psychopathology (treatment for severe depression, suicidality, psychosis); concurrent cognitive behavioral therapy.

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):	01-01-2018
Enrollment:	148
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

-

Ethics review

Positive opinion

Date:	26-02-2020
Application type:	First submission

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
NTR-new	NL8393
Other	ERCPN Maastricht University : ERCPN- OZL_210_01_07_2019

Study results

Summary results

-