The influence of maladaptive emotion regulation on inhibition in patients with eating disorders

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eating disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON48862

Source
ToetsingOnline

Brief title
Emotion regulation and inhibition in eating disorders

Condition

- Eating disorders and disturbances

Synonym
abnormal eating behavior, eating disorders

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: eating disorders, emotion regulation, inhibition

Outcome measures

Primary outcome

Inhibition measured by performance on Stop Signal Task (SST).

Secondary outcome

Not applicable.

Study description

Background summary

Patients with eating disorders seem to have problems with behavioral inhibition, which might have a large influence on their health. It is important to gain more knowledge on their ability to inhibit impulses. Emotions could play a role in this case, as it is well known that patients with eating disorders have disruptions in their affective system and often experience negative emotions. Patients with eating disorders often use suppression as an emotion regulation strategy, which is maladaptive and costs a lot of self-control. Possibly this influences their inhibitiory control, as inhibition also costs self-control. Moreover, it is known that patients with binge-purge related eating disorders often are impulsive, especially in reaction to negativity. This could be due to the use of maladaptive emotion regulation (suppression), as this leads to impaired self-control, and self-control is required for inhibition. In this way, suppressing emotions could lead to impaired inhibition. The link between emotion regulation and inhibition in eating disorders has never been made before in literature, although this could yield important implications for a better understanding of their behavior.

Study objective

The current study aims to examine the influence of suppression as an emotion regulation strategy on inhibition in patients with Anorexia Nervosa restrictive type (AN-R), Anorexia Nervosa binge purge type (AN-BP), Bulimia Nervosa (BN), and Binge Eating Disorder (BED) in comparison to healthy individuals. There are three primary hypotheses. First, it is expected that amongst all participants, the one*s that receive instructions to suppress their emotions show less inhibition than the participants who get no regulation instructions. Second, ED

patients are expected to show less inhibition than control participants. Third, an interaction effect of condition (suppression vs. no instruction) and group (ED patients vs. control) is expected, as suppression leads to impaired inhibition and ED patients will be more likely to suppress their emotions when no regulation instruction is given.

Study design

Participants follow this procedure: they fill out questionnaires regarding demographic variables, clinical characteristics and emotion experience questionnaire. Then, instructions (suppression vs. no instruction) are given and all participants will receive a negative emotion induction by means of a film fragment. This fragment has been used before in psychological research (Evers, Stok, & de Ridder, 2010; Smeets, Candel, & Merckelbach, 2004) and is known to only temporarily elicit negative emotions. Afterwards, emotion checks are measured. Subsequently, participants are asked to perform the SST to measure inhibition. Afterwards, manipulation and emotion checks, and questionnaires regarding eating disorder severity, trait self-control and emotion driven impulsiveness will be administered.

Study burden and risks

Participants* collaboration will include one session (of about 50 minutes) only. Therefore the burden is relatively small. All participants are asked to fill out some questionnaires which can be considered a small burden. Subsequently, participants will experience negative emotions as a result of watching a film fragment. The procedure to evoke negative emotions has been used very frequently by other researchers (e.g., Macht & Mueller, 2007). This specific film fragment has also been used in previous studies (Evers et al., 2010; Smeets et al, 2004). More importantly, no negative consequences were experienced as a result of this procedure. Near the end of the study, participants will perform the SST, a task measuring inhibition that has been used several times before in patients with eating disorders (Bartholdy, Dalton, O*Daly, Campbell, & Schmidt, 2016). The entire procedure is considered safe. Prior to the study, participants are ensured that their treatment will not be influenced in any way by participating in the study and they are told that they can stop participating in the study at any time without reason. At the end of the study, participants will be thoroughly debriefed. They are instructed that they can contact the researchers or the therapist anytime in case of question or any inconveniences as a result of their participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all of the following criteria: All participants are 18 years of age or older and have signed the informed consent. An additional criteria is the diagnosis of either Anorexia Nervosa-Restrictive subtype, Anorexia Nervosa -Binge Purge subtype, Bulimia Nervosa, or Binge Eating Disorder according to the DSM-5. Furthermore, the control group will consist of individuals who are demographically equivalent in age, gender and preferably also education (which is not always feasible) to the patient groups as is determined upon inclusion of several participants in all patient groups.

Exclusion criteria

For all groups, we exclude participants with neurological disorders.
Regarding the groups with patients with eating disorders, we exclude patients who are currently suffering from such a severe depression that they do not experience emotions. Moreover, we will exclude patients who are currently under the influence of alcohol or drugs.

Regarding the control group, we exclude individuals who have psychiatric or psychological problems as measured with the M.I.N.I. through a telephonic interview.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-11-2017
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO Date:	27-10-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-02-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	31-01-2019
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL62106.041.17