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Emotion regulation training in the treatment of obesity in young adolescents: to improve weight control and long-term treatment effects

Submission date
07/12/2017

Recruitment status
No longer recruiting

Registration date
13/12/2017

Overall study status
Completed

Last Edited
18/01/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Childhood obesity is a growing problem, and because of the severity of the negative consequences, it needs to be dealt with as soon as possible. The current treatments for childhood obesity are working, but only in short term and only moderately. Therefore, there is a need to search for the underlying mechanisms to improve the existing treatments. A possible underlying mechanism is emotion regulation. Emotion regulation refers to the processes by which people influence which emotions they have, when they have them, and how they experience and express these emotions. When high levels of stress are regulated in an inadequate way, this can contribute to the development of obesity. Three processes are playing a role. Stress increases the production of the hormone cortisol, which may result in accumulation of fat. Low grade inflammation triggered by emotional distress may result in increased food intake and obesity. Emotional eating (eating to satisfy emotional needs) is also higher in children and adults with obesity, in comparison with average weight individuals. The aim of this study is to find out whether emotion regulation training results in less emotional eating and improves maintenance of weight loss.

Who can participate?
Youngsters aged 10-14 who are involved in a residential obesity treatment program

What does the study involve?
Participants are randomly allocated to receive either care as usual or Emotion Regulation Training (ERT) on top of care as usual. The ERT consists of 10 weekly sessions. Booster sessions are given 1, 3, 6 and 9 months after the end of this training. The participants are tested before and after the training and at 6 and 12 months follow-up to measure their use of emotion regulation strategies and changes in eating behaviour.

What are the possible benefits and risks of participating?
It is expected that the youngsters who receive ERT will use more adaptive emotion regulation strategies with less emotional eating and maintenance of weight loss at 6 and 12 months follow up. Improving the current childhood obesity treatments is the purpose of this study. If the

treatment is found to be effective, the next step is to use it in a larger group of treatment centers.

Where is the study run from?
Zeepreventorium (Belgium)

When is the study starting and how long is it expected to run for?
January 2017 to August 2021

Who is funding the study?
Bijzonder Onderzoeksfonds (Belgium)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
BOF GOA 2017 000101

Study information

Scientific Title
Improving weight control and long-term treatment effects in young adolescents with obesity via emotion regulation training

Study objectives
The trialists expect that adding an emotion regulation training (ERT) to the care as usual results in:
1. The use of more adaptive emotion regulation strategies
2. Less emotional eating

3. Improved weight-loss maintenance
4. Better long-term treatment effects
compared to care as usual only (CAU-only), reflected in different outcome measures (see below) .

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Ghent University Hospital - approval pending

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Childhood obesity

Interventions
The recruitment consists of two waves of children entering the clinic (2018 and 2019). At entrance in the inpatient treatment clinic (July-August 2018, 2019) and after consent, participants are randomly assigned to either the ERT+CAU condition or to a CAU-only control condition. Randomization is stratified on age and gender. Before the beginning of the ERT (September 2018, 2019), the baseline measurement is conducted (August 2018, 2019). The ERT runs from September (2018, 2019) till December (2018, 2019). After the ERT measurements will take place post training (December 2019, 2020), 6-month follow up (February, 2019, 2020) and 12-month follow up (August 2019, 2020).

The intervention concerns an emotion regulation training (ERT): a group training of 10 sessions (duration 2h per session) on top of care as usual, namely the Multidisciplinary Obesity Treatment (MOT). The 10 sessions will be spread over 10 weeks. The groups are formed with max. 4 to 5 children/adolescents.

The ERT (emotion regulation training) will be given at the start of the treatment in the residential treatment center. Booster sessions will be provided at 1 month, 3 months and 6 months after this training. After every session the participants will also receive homework, making them exercising the competence or emotion regulation strategy they learned.

The content of the ERT is based on the training of prof. dr. Mathias Berking (Berking, M. & Whitley, B. (2014). Affect Regulation Training: A Practitioners' Manual. Houten: Springer). In the first 5 training sessions, the following basic competencies are learned: exploring feelings; learning about the basic feelings and the intensity of these feelings; body scan (where do I feel these feelings in my body?); abdominal breathing; emotional awareness; psycho- education on the influences of thoughts – feelings and behavior on each other and psycho- education on the function of emotions: learning to see negative emotions as allies. In the next 4 sessions the

participants will be learned each time 1 emotion regulation strategy: Distraction; Acceptance; Cognitive Reappraisal and Problem Solving. In the last session the basic competencies and the emotion regulation strategies will be recapitulated.

The CAU (care as usual) consists of:
1. Psycho-education on food and physical activity
2. Therapy sessions on diet/healthy eating
3. Physical activity (4h a day) and healthy food habits
4. Parents are involved in therapy
5. Protocols about psychological aspects: problem solving, social competencies and self-worth
6. Individual sessions with a psychologist (every 2 weeks = Cognitive Behavioral Therapy)

Intervention Type
Behavioural

Primary outcome(s)
1. Changes in the use of emotion regulation strategies: as measured on:
1.1. The FEEL-KJ questionnaire, measured at baseline, post, 6 and 12 months
1.2. Idiosyncratic measures (diary), measured between each ERT session, weekly 10 times from September to December
1.3. An experimental test after a mood induction movie, measured at baseline and post training
2. Changes in psychophysiological measures that represent emotion regulation as measured by:
2.1. Heart rate variability, measured at baseline, post and 6 months
2.2. Cortisol levels, measured at baseline, post and 6 months
3. Changes in eating behavior as measured on:
3.1. The NVE questionnaire, child and parent reporting, measured at baseline, post, 6 and 12 months
3.2. The SSES and SEES questionnaire, measured at baseline, post, 6 and 12 months
3.3. Idiosyncratic measures (diary), measured between each ERT session, weekly 10 times from September to December
3.4. Experimentally with a foodlab after a mood induction movie, measured at baseline and post training
4. Changes in attention for eating cues as measured by:
4.1. An attentional task, measured at baseline and post training
5. Changes in metabolomics:
5.1. Blood (parameters are inflammation; energy (leptin, ghrelin); NPY, cholesterol and triglycerides), measured at baseline and 6 months
5.2. Feces, measured at baseline and 6 months

Key secondary outcome(s))
1. Weight index as measured by:
1.1. BMI, measured at baseline, post, 6 and 12 months
1.2. Waist, measured at baseline, post, 6 and 12 months
2. Psychological wellbeing as measured by:
2.1. Different questionnaires (CBCL, YSR, CDI), measured at baseline, 6 and 12 months
3. Sleep pattern as measured by:
3.1. The CRSQ, measured at baseline, 6 and 12 months

Completion date
31/08/2021

Eligibility

Key inclusion criteria
1. Primary obesity (minimum 60% overweight at intake for obesity treatment in the clinic)
2. Age between 10 and 14 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
14 years

Sex
All

Total final enrolment
118

Key exclusion criteria
1. Comorbid medical disorders that cause (a part of) the weight gain (i.e. serious thyroid problems)
2. Youngsters with medical problems where obesity is secondary

Date of first enrolment
01/03/2018

Date of final enrolment
01/07/2020

Locations

Countries of recruitment
Belgium

Study participating centre
Zeepreventorium
Koninklijke Baan 5

De Haan
Belgium
8420

Sponsor information

Organisation
Ghent University

ROR
https://ror.org/00cv9y106

Funder(s)

Funder type
Research organisation

Funder Name
Bijzonder Onderzoeksfonds

Alternative Name(s)
Special Research Fund, BOF

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Belgium

Results and Publications

Individual participant data (IPD) sharing plan
The data is saved on a server of the University Ghent. Three types of data will be stored: questionnaire data, behavioural data and physiological data. Raw data of the questionnaires and behavioural data will be saved as .txt files, the physiological data will be stored as .edf files. Data storage fact sheets are used to document the meta-data. These files describe the transition from raw data to processed data and contain information about the variables and the encompassing datasets. The data storage fact sheets are stored on the local server of the department of the UGhent. Data about the informed consents, and the file linking participants

numbers and names/contact information will be collected in a password-protected file. In this study there will be personal or confidential data collected. No personal information of participants will be coupled to the gathered data in any way. Participants' codes will be in the entire study (with the informed consents as only exception). The personal information will be saved according the law of privacy of 08/12/92. Participants will be informed about this in the informed consent. For sharing data, a protected USB flash drive is provided, filtered according the limitations as stated in the privacy and ethical commissions.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/02/2020	12/02/2020	Yes	No
Participant information sheet	Participant information sheet		18/01/2024	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes