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WELCOME: improving WEight controL and CO-Morbidities in children with obesity via Executive function training

Submission date
10/05/2017

Recruitment status
No longer recruiting

Registration date
16/06/2017

Overall study status
Completed

Last Edited
09/07/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
As the prevalence and negative consequences of childhood obesity are severe, this problem needs to be tackled as soon as possible. The current treatments for obesity are successful but only moderately and in the short term. Improving executive functioning may be an answer to the question "why is it still so difficult for obese youngsters to lose weight and to control it on a long term?" Executive functioning is an umbrella term to represent brain processes that allow people to control themselves. This process can be crucial in the origins and maintenance of obesity. Obese youngsters often have more difficulty with self-control when confronted with unhealthy temptations. More specifically, they seem to have an inhibition and attention bias. Inhibition is the capacity to suppress the impulsive urge to react, in this case when tempted towards unhealthy food (i.e., not grasping food when seeing hamburger advertisements). Next, they also seem to have attentional biases. Attention is the capacity to (re)direct focus, in this case away from unhealthy food (i.e., not thinking about eating when seeing hamburger advertisements). Obese children and adults with obesity, in comparison to normal-weight persons, have more inhibition and attention problems, and are more impulsive and distracted when confronted with those temptations. There is a lot of evidence to support this. Unfortunately, there hasn't been a lot of evidence for youngsters, and these insights are not used in current treatment. The aim of this study is to find out whether executive function training results in better weight control and less illness.

Who can participate?
Obese youngsters aged 8 to 18 who are already receiving treatment

What does the study involve?
Participants are randomly allocated to receive one of two forms of executive function training on top of their usual treatment. One group receives the training tasks with all active components (inhibiting responses toward unhealthy food and refocusing attention away from unhealthy). The other group receives the same training tasks but without the 'active ingredients'

(stimuli are equally divided towards neutral or unhealthy food). This training lasts 14 weeks, and the participants are followed up until 6 months afterwards to measure their executive functioning, weight and eating behaviours.

What are the possible benefits and risks of participating?
Youngsters who receive the active elements of the training are expected to gain more self-control, lose more weight and have more healthy eating behaviour in comparison to the other group. If this extra treatment is found to work, the goal is to use this treatment in a larger group of treatment centres. There are no known risks from the brain fitness tasks. The data collection is carried out and supervised by trained medical personnel and has no extra health risks.

Where is the study run from?
1. Zeepreventorium (Belgium)
2. Jan Palfijn Hospital (Belgium)
3. University Hospital of Antwerp (Belgium)

When is the study starting and how long is it expected to run for?
January 2017 to December 2020

Who is funding the study?
Fonds Wetenschappelijk Onderzoek (Belgium)

Who is the main contact?
Mrs Tiffany Naets
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
150179

Study information

Scientific Title
Improving weight control and co-morbidities in children with obesity via executive function training: a randomised controlled trial

Acronym
WELCOME

Study objectives
Active executive function (EF) training results in better weight control and less co-morbidities than active-control EF training.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Pilot study: Commissie voor Medische Ethiek UGent/UZ Gent, 03/05/2017, ref: 2017/0305
Full study: approval pending

Study design
Interventional longitudinal multicentre blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Participants are randomized to either an experimental group or an active control group (50/50, 30/10 in pilot) via the OPEN CLINICA computer program. The executive function training consists

of two tasks (Go-No-Go inhibition task and Dot-Probe attention task) on top of care as usual (Multidisciplinary Obesity Treatment [MOT]). Both groups do both tasks. The experimental group receives the tasks with all active components (inhibiting responses toward unhealthy food and refocusing attention away from unhealthy). The active control group receives the same tasks that last as long, but without the 'active ingredients' (equally divided stimuli towards neutral or unhealthy food). Participants are followed up at 2 and 6 months.

Intervention Type
Behavioural

Primary outcome measure
Weight index (BMI, adjusted, calibrated) measured at T0-T4

Timepoints:
T0 = baseline (at the intake in the treatment centre)
T1 = start training (in between there is approximately 4-6 months, depending on the treatment centre)
T2 = end of the intensive training (after 6 weeks intensive training and when the follow-up and booster starts)
T3 = after 2 months/8 weeks follow up and performing the tasks once a week in booster sessions
T4 = after 6 months follow up

Secondary outcome measures
1. IQ, measured using Raven Progressive Matrices (task for the participant) at T0-T4, except for the outpatient centers that don’t measure them at T1
2. Depression and anxiety, measured using ASEBA questionnaires: Youth Self Report (YSR) and Child Behavior Checklist (CBCL) and the Children Depression Inventory (CDI) self-report at T0-T4, except for the outpatient centers that don’t measure them at T1
3. Self-worth, measured using CBSA and CBSK, translated version of Self-Perception Profile at T0-T4, except for the outpatient centers that don’t measure them at T1
4. Executive functioning, measured using:
4.1. A questionnaire (Effortful Control Scale (ECS) self-report, BRIEF (Behavior Rating Inventory of Executive Function) = BRIEF-Parent version and BRIEF-teacher version [for the educators at the Zeepreventorium]) at all timepoints, with exclusion of the T1 measurements for the outpatient settings
4.2. Inhibition and attention measurements from the EF tasks (Go-No-Go and Dot Probe Task), errors and reaction times at T0, T1, T2, T3 and T4
5. Eating behaviors, measured using Ch-EDE-Q self-report and Dutch Eating Behavior Questionnaire (“NVE” in Dutch) at T0-T4, except for the outpatient centers that don’t measure them at T1

Added 21/06/2017:
Medical variables:
1. Waist and hip measurements at T1 + T3
2. Blood and pulse pressure, measured with automatic meters
3. Puberty status: clinical stages (Tanner)
4. Tonsillar hypertrophy: clinical stages (Brodsky)
5. Blood measurements (venipuncture)
6. Urine (urine sample)
7. Lung function, measured with spirometry and full body plethysmography
8. Vascular function, measured with ENDO-Pat

9. Sleep pattern, measured with ApneaLink and questionnaire
10. Body composition, measured with a Body Composition Monitor (BCM)

Timepoints:
T0 = baseline (at the intake in the treatment centre)
T1 = start training (in between there is approximately 4-6 months, depending on the treatment centre)
T2 = end of the intensive training (after 6 weeks intensive training and when the follow-up and booster starts)
T3 = after 2 months/8 weeks follow up and performing the tasks once a week in booster sessions
T4 = after 6 months follow up

Overall study start date
01/01/2017

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Obese youngsters ((a)BMI > 120)
2. Age 8 - 18
3. Both male and female
4. Following treatment (outpatient or inpatient)

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Pilot N = 40 (Zeepreventorium) + N = 200 (100 Zeepreventorium, 50 Jan Palfijn, 50 UZA)

Total final enrolment
302

Key exclusion criteria
Comorbid medical disorders that cause (a part of) the weight gain (i.e. serious thyroid problems)

Date of first enrolment
01/04/2017

Date of final enrolment
28/02/2020

Locations

Countries of recruitment
Belgium

Study participating centre
Zeepreventorium
Koninklijke Baan 5
De Haan
Belgium
8420

Study participating centre
Jan Palfijn Hospital ("Jan Palfijn")
Watersportbaan 5
Ghent
Belgium
9000

Study participating centre
University Hospital of Antwerp ("UZA")
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2650

Sponsor information

Organisation
Ghent University

Sponsor details
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Sponsor type
University/education

Website
https://www.vopspsy.ugent.be/en/

ROR
https://ror.org/00cv9y106

Funder(s)

Funder type
Government

Funder Name
Fonds Wetenschappelijk Onderzoek

Alternative Name(s)
Research Foundation Flanders, Flemish Research Foundation, FWO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Belgium

Results and Publications

Publication and dissemination plan
First year (2017) next to data collection:
1. Pilot study: writing information for participants and their parents (in the form of education folders and flyers) for the pilot
2. Website introduction
3. Manuscripts of the pilot study

Second year (2018) next to data collection and analysis:
1. Protocol paper
2. Information for the participants and their parents (in the form of education folders and flyers)
3. Teaching PowerPoints

Third year (2019) next to data collection and analysis:
1. Feasibility analyses
2. Writing guidelines and a manual
3. Train the trainer materials
4. Educational videos for website
5. Distributing knowledge newsletter
6. Information for partners
7. Press communications
8. Manuscript on executive functioning (after training and 2-month follow-up)

Fourth year (2020):
1. Manuscripts on executive functioning and comorbidities (after training and 2-month follow-up)
2. Manuscript on 6-month follow-up

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Tiffany Naets (primary researcher), Dr Leentje Vervoort (co-promotor) and Prof. Dr Caroline Braet (promotor).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Adherence and barriers	01/01/2020	17/08/2022	Yes	No
Results article		23/12/2021	17/08/2022	Yes	No
Protocol article		29/08/2018	23/08/2022	Yes	No
Results article		05/06/2023	19/06/2023	Yes	No
Results article		05/06/2023	17/07/2023	Yes	No
Other publications	Reliability of the dot probe task using an obese subset from this study and a convenience non-obese subset	03/03/2021	09/07/2025	Yes	No
Results article	Risk factors for dropouts and treatment outcomes	13/06/2022	09/07/2025	Yes	No