

The effect of a cognitive bias modification training for children in a residential obesity treatment program

Submission date 21/08/2015	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 10/09/2015	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 10/09/2015	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

The World Health Organisation (WHO) has stated that childhood obesity is one of the most serious global health problems in the present day. Studies have shown that most childhood obesity treatment and prevention programmes only work in the short term, and do not reduce the risk for future weight gain. The reason for this is thought to be because children feel a greater "reward" when eating unhealthy food, as it gives them more pleasure than eating healthy food. People tend to try to "avoid" things that are thought of as being unpleasant by pushing them away, and to "approach" things that are pleasant by pulling them towards them. It is thought that this is what is happening with unhealthy and healthy foods. The Approach-Avoidance Task (AAT) is where participants are shown an image on a computer screen, and are asked to respond as quickly as they can by pushing or pulling a joystick. This test works on the principal that it is hard-wired in our brains to automatically "approach" things we see as being pleasant, and to automatically "avoid" things which we see as being unpleasant. Within this study, the AAT is embedded into a video game. By giving children "rewards" within the game for "approaching" the healthy food instead of "avoiding" it, it may be possible to re-train these thought patterns. The study aims to find out whether children using this system will be able to maintain lower weights achieved from taking part in childhood obesity treatment and prevention programmes.

Who can participate?

Significantly overweight children with a normal IQ score.

What does the study involve?

Children that have been attending a clinic to treat obesity problems are randomly assigned into the AA-training plus usual care group, or the Tetris usual care group (control group). The AA-training involves playing a videogame for 10 half hour sessions, designed to train them to "approach" pictures of healthy foods (e.g. carrot) and "avoid" unhealthy foods (e.g. chips). The children in the control group will play 10 half hour sessions of Tetris. Changes in behaviour of the children throughout the trial are monitored. The weight of the children is also measured before the training, after the training, and 12 weeks after the training is complete.

What are the possible benefits and risks of participating?

A possible benefit is that the AA-training may help children to develop a better attitude towards healthy eating. There are no significant risks of participating in the study.

Where is the study run from?

Zeepreventorium (Belgium)

When is the study starting and how long is it expected to run for?

January 2012 to September 2013

Who is funding the study?

Agency for Innovation by Science and Technology (IWT) of Flanders (Belgium)

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Effectiveness of adding an Approach Avoidance Training with game elements to a residential childhood obesity treatment.

Study objectives

We expect a decrease in approach bias and craving for high caloric food and this will be associated with better weight loss maintenance at follow-up in those participants randomized to the approach avoidance (AA) training condition compared to those in the control condition.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of Ghent University, 27/06/2014, ref: 2014/34

Study design

Single-centre single-blinded randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Childhood obesity, more specifically the maintenance of weight loss after therapy.

Interventions

1. Approach Avoidance (AA)-Training. An AA game training was developed, based on the AA task (an adaptation of Wiers, Rinck, Kordts, Houben, and Strack (2010), and used to re-train the children's approach tendencies towards unhealthy food in 10 training sessions. Each training session took approximately 30 minutes and consisted of a training block of 12 minutes, followed by 3 minutes of 'game time break' (GTB), then another training block of 12 minutes and a final 3 minutes GTB. During these GTBs, the children were allowed to do bonus training trials to collect more points or to use their points in an online game. The session ended with an additional bonus block of 3 minutes maximum where the children were allowed to train for extra points, which could only be spent in the next session. Including bonus trials, the participants trained on 292 trials on average (10 % of which were filler trials) per session. Each correct response (i.e., matching the tilt with the correct response button) resulted in points, with bonus for speed e.g., 1 point for a correct reaction time above 1200 ms until 5 points for a correct reaction time below 300 ms. The AA-training used a 100/0 matching between tilt and content, i.e. all unhealthy pictures were tilted to match the push (avoid) instruction and all the healthy pictures were tilted to match the pull (approach) instruction. A set of 8 unique pictures of healthy food and 8 unique pictures of unhealthy food was used during each session. At the start of each training session the child was given a daily goal to gain a certain number of points, which upon achievement would earn them bonus points. The AA-training was embedded inside an online game which allowed the children to use points earned through training to build a virtual city of little houses, trees, roads, etc. (see Figure 2). A social element was added by letting the children view the cities of other participants, which they were also allowed to rate with a "thumbs up".

2. Tetris The computer game 'TETRIS' was downloaded from www.TheTetrisGame.com and served as the control condition. This was done to allow us to keep two aspecific variables (screen time, game element) constant in both conditions.

Intervention Type

Behavioural

Primary outcome(s)

Weight loss maintenance at 3 months follow up. The Body Mass Index (BMI) ($\text{weight}/\text{height}^2$) is determined for each child entering the clinic (admission), one week before the start of the intervention (pre-training), one week after the start of the intervention (post-training), and 12 weeks follow up.

Key secondary outcome(s)

1. Changes in action tendencies, measured using an Approach Avoidance Task (AAT) measured one week before the start of the intervention (pre-) and one week after the start of the intervention (post-)
2. Changes in attentional bias, measured using a Visual Probe Task (VPT) at pre- and post intervention
3. Changes in children's implicit pleasant and unpleasant associations of unhealthy food, measured using a single category implicit association task (SC-IAT) at pre- and post intervention
4. Changes in craving, measured using self-report questionnaires (G-FCQ-S and G-FCQ-T) at pre- and post intervention

Completion date

30/09/2013

Eligibility**Key inclusion criteria**

1. Primary obesity (minimum 60% overweight at intake for obesity treatment in the clinic)
2. Aged between 10 and 15 years
3. IQ within the normal range as measured with the Raven Progressive Matrices (RPM; Raven, 1938)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

10 years

Upper age limit

15 years

Sex

All

Key exclusion criteria

1. IQ outside the normal range as measured with the Raven Progressive Matrices (RPM; Raven, 1938)
2. Presence of pervasive developmental disorders

Date of first enrolment

15/02/2013

Date of final enrolment

15/03/2013

Locations

Countries of recruitment

Belgium

Study participating centre

Zeepreventorium

Koninklijke Baan 5

De Haan

Belgium

8420

Sponsor information

Organisation

Agency for Innovation by Science and Technology (IWT) of Flanders

Funder(s)

Funder type

Government

Funder Name

Agency for Innovation by Science and Technology (IWT) of Flanders

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Stored in repository