Executive functioning in normal-weight, overweight and obese children in relation to food and non food-related stimuli. Randomized controlled pilot study to evaluate the influence of a food-specific inhibition task on (high-calorie) food intake

Published: 06-11-2014
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First objective: this study will compare executive functioning of normal-weight participants (controls) to overweight/obese participants, in relation to food related stimuli and non food-related stimuli.Second objective: this study will examine if...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40856

Source
ToetsingOnline

Brief title
Executive functioning in normal-weight, overweight and obese children

Condition

- Other condition
- Cognitive and attention disorders and disturbances

Synonym

Obesity; (extreme)overweight

Health condition

obesitas en overgewicht bij kinderen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Executive Functioning, Food-Related Stimuli, Obesity

Outcome measures

Primary outcome

First: response time and inhibition errors during EF tasks, are the two most important parameters to examine EF in normal weight and overweight/obese children.

Second: to evaluate whether EFT, in de form of a Go/No-Go inhibition task, can influence behavior towards food-stimuli; response time and inhibitions errors during the Go/No-Go task will be compared between the two conditions (a high-calorie food/go condition or high-calorie food/no-go condition) and two groups (normal/overweight and obese children). To evaluate whether EFT can influence behavior towards actual food, food intake (measured in gram) will be compared between the two conditions and the two groups.

References and further information can be found in the protocol.

Secondary outcome

Other study parameters:

- results from the NVE-K questionnaire

- BMI, which will be measured using a scale and tapeline. Participants were considered overweight or obese according to cut off points developed by Cole (Cole, Bellizzi, Flegal, & Dietz, 2000).

References and further information can be found in the protocol.

Study description

Background summary

Obese children display a variety of health problems including cardiovascular problems, psychosocial problems and disturbance in executive functioning (Liang, Matheson, Kaye, & Boutelle, 2013; Reilly, et al., 2003; Smith, Hay, Campbell, & Trollor, 2011). Results of (lifestyle)interventions in overweight and obese children vary; have high drop-outs and great risk for recidivism (de Niet, et al., 2011; Nederkoorn, Braet, Van Eijs, Tanghe, & Jansen, 2006; Smith, et al., 2011). Recent studies indicate that overweight and obese children show disturbances in different aspects of executive functioning. Executive Function Training (EFT) has been found to alter responses toward food related stimuli, lead to a decline in food consumption and can eventually lead to a reduction in weight (Houben & Jansen, 2011; Verbeken, Braet, Goossens, & van der Oord, 2013). Therefore, EFT could be a new tool to support changes in a healthy lifestyle.

References and further information can be found in the protocol.

Study objective

First objective: this study will compare executive functioning of normal-weight participants (controls) to overweight/obese participants, in relation to food related stimuli and non food-related stimuli.

Second objective: this study will examine if EFT, in de form of a Go/No-Go inhibition task, can alter responses towards food(stimuli) in normal-weight,

overweight and obese children.

References and further information can be found in the protocol.

Study design

First: observational pilot study (2x30). An independent samples t-test will be used to compare normal-weight participants to overweight/obese participants of performance of different EF tasks. Participants will be matched on level of school performance and age. It is hypothesized that overweight/obese participants will show a lower performance on the measures of EF. In addition, it is hypothesized that participants will show an interference effect (more inhibition errors and slower reaction times) towards food stimuli.

Second: experimental study design, randomized controlled pilot study (2x2x15). At the start of the Go/No-Go task participants are randomly assigned to either a high-calorie food/go condition or high-calorie food/no-go condition; depending on the condition, participants are either instructed to inhibit high-calorie food and respond to other food stimuli (vegetables and fruit) or respond to high-calorie food and inhibit other food stimuli. Performance, measured in reaction time and amount of inhibition errors, will be compared between the two conditions and two groups (normal/overweight/obese children) using a one-way between groups analysis of variance (ANOVA). Besides these two parameters, the food intake calculated amount of calories will be compared between the two conditions and groups. It is hypothesized that participants in the condition high-calorie food/no-go condition will have a decreased food consumption of the high calorie food. A more detailed description of the study design can be found in section 8.

References and further information can be found in the protocol.

Study burden and risks

The burden and risk associated with participation are minimal. Participants will visit one of the participating medical centre (Erasmus MC, SFG, LUMC) once, for approximately 30-40 minutes. Participants will complete the NVE-K, 4 EF tasks and a taste test. In addition, weight and height will be measured.

References and further information can be found in the protocol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- be 10 to 14 years of age

Exclusion criteria

Exclusion criteria
A potential subject who meets any of the following criteria will be excluded from participation in this study:
- no known psychiatric disorders
- medication; endocrine disorders that require chronic medication

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO Date:	06-11-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-10-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL48931.078.14