A double-blind randomized trial of the efficacy of replacing sugary drinks by low sugar alternatives on body weight and fat mass in school schildren aged 5-10 years

Published: 24-04-2009
Last updated: 06-05-2024

To test the effect of replacing sugar containing beverages by *diet* beverages containing non-caloric sweeteners on body weight and fat mass in school children aged 5-10 years. In addition we will examine the food intake of all participants at lunch...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33427

Source
ToetsingOnline

Brief title
DRINK-study

Condition

- Other condition

Synonym
obesity, overweight

Health condition

overgewicht/obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: KNAW en ZonMw ,Nederlandse Hartstichting

Intervention

Keyword: children, intervention, overweight, sugar sweetened beverages

Outcome measures

Primary outcome

The primary outcomes of the study are the children*s bodyweight (body mass index, corrected for age), waist circumference, skin folds and bioelectrical impedance. These outcomes will be measured four times during the study, at the start, after 6, 12 months and at the end of the study. As a secondary outcome we will also assess food intake of the children at lunch time, shortly after the morning break when the children have consumed the study drinks. This outcome will be measured at the start and at the end of the study.

Secondary outcome

As a secondary outcome we will also assess food intake of the children at lunch time, shortly after the morning break when the children have consumed the study drinks. This outcome will be measured at the start and at the end of the study.

Study description

Background summary

Liquid carbohydrates (including soft drinks as well as fruit juices) are thought to be less satiating then solid carbohydrates (e.g. bread or fruits).

Calories from sugary drinks might not be compensated for by eating less at subsequent meals. In this way liquid carbohydrates might be one of the causes of overweight and obesity in children. However government policies to reduce intake have been less than firm. One reason may be that the evidence for an effect of sugary drinks on body weight rests mostly on observational epidemiological studies and a few short term interventions. Therefore, we propose the first double-blind, long term, randomized controlled trial. The hypothesis of this trial is that intake of liquid carbohydrates is not compensated for sufficiently by reducing caloric consumption for other foods. This leads to incomplete compensation for the energy ingested and eventually results in the excess weight gain.

Study objective

To test the effect of replacing sugar containing beverages by *diet* beverages containing non-caloric sweeteners on body weight and fat mass in school children aged 5-10 years. In addition we will examine the food intake of all participants at lunch time. This trial is a strict test of the physiological effects of liquid carbohydrates on body weight. Changes in body weight due to social and psychological cues and expectations will be eliminated since the trial is blinded.

Study design

A double-blind, long term, randomized controlled trial

Intervention

Six hundred healthy children (5-10 years) will be divided randomly into 2 groups. Group 1 (n=300) receives 250 mL per day of sugar-containing drinks (Unilever peach drink, Unilever mango drink, Unilever lemon drink). Group 2 (n=300) receive 250 mL per day of light drinks (Unilever peach drink light, Unilever mango drink light, Unilever lemon drink light). The drinks for group 2 are identical looking. The light drinks are sweetened with artificial sweeteners. The drinks will be consumed during the morning break during the weekdays at school and at home during weekends and holidays. The intervention period for both groups will be 18 months.

Study burden and risks

All drinks are safe. The amounts of artificial sweeteners in the light drinks are in accordance with governmental regulations for foods and drinks. The measurements are non-invasive and there are no risks associated to these measurements. There is no direct clinical benefit from participating in this study. However this trial might have a decisive impact on policy and medical practise and lead to effective interventions that contribute to the prevention

of overweight and obesity in children.

Contacts

Public
Vrije Universiteit

De Boelelaan 1085
1081HV
NL
Scientific
Vrije Universiteit

De Boelelaan 1085
1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Healthy school going boys and girls
- Age 5 years and older, children still have to be in elementary school at the end of the study.
- Children who already habitually consume 250 mL per day or more of sugary drinks.

Exclusion criteria

- Using medication or under medical treatment for obesity
- Any acute or chronic disease such as diabetes, grow disorders, celiac disease, or serious

gastro-enterology (for example inflammatory bowel disease).
- Medical history or surgical events known to interfere with the study
- Participation in another intervention trial up to 3 months before and during the study if the intervention interferes with the current study
- Physical disabilities that hamper the measurements
- Intention to change location of residence and primary school during the study period

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2009
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL26880.029.09