

A Study of the Effect of Replacing Sugary Drinks by Low-Sugar Alternatives on Body Weight and Fat Mass in Children (DRINK).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27678

Source

Nationaal Trial Register

Brief title

DRINK study

Health condition

obesity
overweight

Sponsors and support

Primary sponsor: VU University Amsterdam

Source(s) of monetary or material Support: ZonMw: The Netherlands Organisation for Health Research and Development

Dutch Heart Foundation

KNAW: Royal Netherlands Academy of Arts and Sciences

Intervention

Outcome measures

Primary outcome

BMI z-score.

Secondary outcome

1. Waist circumference;
2. Bioelectrical impedance (% fat mass);
3. Sum of four skinfolds (mm);
4. Dental health;
5. Sensory evaluation.

Study description

Background summary

Obesity results from an imbalance between energy intake and energy expenditure. There is much speculation about foods that are particularly fattening, and sugary drinks are seen as major culprits. It is hypothesized that a high intake of calories from sugary drinks would not be compensated for by reduced food intake at subsequent meals. As a result body weight would increase. In this double-blind, long term, randomized controlled trial the effect of replacing sugar-containing beverages by low-sugar alternatives on body weight and fat mass in children will be investigated.

Study objective

The hypothesis is that intake of liquid carbohydrates is not compensated sufficiently by reducing caloric consumption from other foods. This leads to incomplete compensation for the energy ingested and eventually results in weight gain.

Study design

0, 6, 12 and 18 months.

Intervention

1. Intervention 1: 250 mL per day of sugar-containing lemonade;

2. Intervention 2: 250 mL per day of lemonade low in sugar. The low-sugar drinks are sweetened with artificial sweeteners.

The intervention will take 18 months.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

1. Using medication or under medical treatment for obesity;
2. Any acute or chronic disease such as diabetes, growth disorders, celiac disease, or serious gastroenterological diseases;

3. Medical history or surgical events known to interfere with the study;
4. Participation in another intervention trial up to 3 months before and during the study, if the intervention interferes with the current study;
5. Physical disabilities that hamper the measurements;
6. 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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2009
Enrollment:	600
Type:	Actual

Ethics review

Positive opinion	
Date:	04-05-2009
Application type:	First submission

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
NTR-new	NL1695
NTR-old	NTR1796
Other	ZONMW / NHS : 120520010 / 2008B096
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A