

# 'Be active, eat right', Lifestyle, growth and health of children aged 4 to 7

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25821

### Source

Nationaal Trial Register

### Brief title

N/A

### Health condition

Prevention, Obesity, Overweight, Children, Youth-Health-Care, Effectiveness, Efficiency (in Dutch: Preventie, Obesitas, Overgewicht, Kinderen, Jeugdgezondheidszorg, Effectiviteit, Efficiëntie)

## Sponsors and support

**Primary sponsor:** dr. H. Raat, Erasmus MC, Universitair Medisch Centrum Rotterdam, Afdeling Maatschappelijke Gezondheidszorg

**Source(s) of monetary or material Support:** ZonMW

## Intervention

## Outcome measures

### Primary outcome

Regarding the evaluation of the prevention protocol:

1. Body Mass Index (BMI)

2. Waist circumference

Regarding the evaluation of the detection protocol:

1. Labels normal weight, overweight and obesity according to the detection protocol

## **Secondary outcome**

Regarding the evaluation of the prevention protocol:

1. Levels of the four target overweight reducing and inducing behaviours, i.e. being physically active, eating breakfast daily, drinking sweet beverages and watching TV or playing on a computer

2. Health-related quality of life

3. Attitudes of parents regarding the four target behaviours mentioned by 1.

4. Absence or presence of indicators of negative side effects, i.e. worry, stigmatisation, lowered self-esteem and development of relative underweight.

Regarding the evaluation of the detection protocol:

1. Sensitivity and specificity of the labels normal weight, overweight and obesity according to the detection protocol.

## **Study description**

### **Background summary**

Background.

The prevalence of overweight and obesity in children has at least doubled in the past 25 years. In Dutch Youth Health Care there was an urgent need for standardized protocols for the detection and prevention of overweight and obesity in children. In 2004 and 2005 a detection protocol ('Signaleringsprotocol Overgewicht') and a prevention protocol ('Overbruggingsplan') were developed. This study aims to evaluate the predictive value of the detection protocol and to evaluate the effects of the prevention protocol.

Objective.

In this study we will evaluate the effects of the prevention protocol in children with overweight in terms of measures of body fatness (BMI and waist circumference) and in terms of the four target behaviours, which reduce and induce overweight (i.e. being physically active, eating breakfast daily, drinking sweetened beverages and watching TV or playing on a computer). Secondly, within the control group we will evaluate the predictive value of the detection protocol by comparing the labels normal weight, overweight and obesity according to the detection protocol at the age of 5, with these labels at the age of 7. In addition we will conduct a process evaluation and a cost-effectiveness analysis will be performed.

## Methods/design.

The design of the study is a cluster-randomised trial with the YHC-teams as the unit of randomisation and a follow-up period of 2 years. Prior to the preventive health check all parents will receive the informed consent form for participating in the study and a two-paged questionnaire to assess some basic socio-demographic variables and health behaviours. During the preventive health check the YHC-teams in both the intervention group and control group will apply the detection protocol (which includes measuring the primary outcome measurements BMI and waist circumference) and will label children as normal weight, overweight or obese. The YHC-teams in the intervention group will then offer the parents of children with overweight the prevention protocol, which includes a structured three-YHC-visits-program. The YHC-teams in the control group will offer the parents of children with overweight usual care as offered by the YHC-teams before implementing the prevention protocol. Questionnaires to assess the secondary outcome measurements (the levels of the four target behaviours, health-related quality of life, the attitudes of parents regarding the four target behaviours and the absence or presence of indicators of negative side effects) will take place at baseline and after 12 and 24 months of follow-up. After 24 months of follow-up measures of BMI, waist circumference and labelling of the participating children with normal weight, overweight or obesity will be repeated.

## Study objective

- The detection protocol applied at age 5 (second year of elementary school) predicts the presence of overweight at age 7 (fourth year of elementary school).
- The prevention protocol applied to parents of overweight children aged 5 (second year of elementary school) results in a better lifestyle at age 6 (third year of elementary school) and age 7 (fourth year of elementary school) and results in a relatively lower BMI and waist circumference at age 7 compared to children in the control group who receive usual care

## Study design

Time points measurements:

- Age 5 (second year of elementary school): preventive health check (September 2007 – June 2008)

- Age 6 (third year of elementary school): first follow-up measurement (September 2008 – June 2009)
- Age 7 (fourth year of elementary school): second follow-up measurement (September 2009 – June 2010)

## **Intervention**

The YHC-teams in both the intervention group and control group will apply the detection protocol and label children as normal weight, overweight or obese. The YHC-teams in the intervention group will then offer the parents of children with overweight the prevention protocol, which includes a structured three-YHC-visits-program. The YHC-teams in the control group will offer the parents of children with overweight usual care as offered by the YHC-teams.

## **Contacts**

### **Public**

Erasmus MC, Universitair Medisch Centrum Rotterdam  
Afdeling Maatschappelijke Gezondheidszorg  
Kamer AE-131  
Postbus 2040  
L. Veldhuis  
Rotterdam 3000 CA  
The Netherlands  
+31 (0)10 7038453

### **Scientific**

Erasmus MC, Universitair Medisch Centrum Rotterdam  
Afdeling Maatschappelijke Gezondheidszorg  
Kamer AE-131  
Postbus 2040  
L. Veldhuis  
Rotterdam 3000 CA  
The Netherlands  
+31 (0)10 7038453

## **Eligibility criteria**

### **Inclusion criteria**

The study population consists of all children and their parents who will be invited for a

preventive health check by the 44 participating YHC-teams of the 9 participating Municipal Health Services in the Netherlands, during the second year of elementary school during school year 2007/2008.

## Exclusion criteria

For the prevention protocol and the questionnaires used in the study the parents should have basic Dutch language skills.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	18-09-2007
Enrollment:	7200
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	26-02-2007
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	NL897
NTR-old	NTR921
Other	ZonMw project number : 505011098355
ISRCTN	ISRCTN04965410

## Study results