

Evaluation of a school-based multi-component programme to prevent overweight in primary school children

Published: 22-07-2009

Last updated: 11-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON33761

Source

ToetsingOnline

Brief title

Prevention of overweight in primary school children

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym

obesity, overweighth

Research involving

Human

Sponsors and support

Primary sponsor: Zorgonderzoek Nederland (ZON)

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: diet, overweight, physical activity, school

Outcome measures

Primary outcome

Nutrition behaviour:

- eating of snacks and sweets, and drinking of soft drinks and sweetened dairy products in between regular meals
- consumption of fruits, fruit juices and vegetables
- daily breakfast

Physical activity:

- time spent at playing outside the home
- time spent at walking or cycling to and from school
- time spent at sports

Inactivity:

- time spent at watching TV, DVD, using the computer and playing computer/videogames

Attitudes, self-efficacy, perceived social norms and intention.

Secondary outcome

Length

Weight

Waist circumference

Study description

Background summary

A considerable increase in the prevalence of overweight and obesity has been observed among children in the Netherlands. An important period in the development of overweight and obesity is the pre-adolescent period. A multitude of interventions to prevent overweight in children exist, however evidence of effectiveness is often missing. An evaluation study is proposed to test the effectiveness, costs, and feasibility of a multi-component strategy that includes a combination of educational and ecological activities directed at physical activity, nutrition behaviour and causes of inactivity in primary school children, 9-11 years old. In this project we will compose a multi-component strategy to prevent overweight from best practices materials drawn from existing Dutch prevention programmes. The American evidence based programme Planet Health will provide the framework to give this multi-component strategy a sound theoretical foundation. An evaluation study will be conducted on the multi-component overweight prevention strategy to test the feasibility and effectiveness of the programme and assess programme costs in the Dutch setting.

Study objective

The objectives of the project are to evaluate the effectiveness of the school-based multi-component programme aimed at the promotion of healthy nutrition behaviours, a reduction of inactivity, i.e. of television watching and computer use, and the promotion of physical activity to prevent overweight in primary school children 9-11 years old, and finally to assess the process whereby the programme is implemented.

Study design

Effect evaluation

Schools will be assigned randomly to an intervention group or a control group. The intervention schools will successively implement the multi-component programme in groups 6 and 7 the year after. Control schools will have their "usual care". They will continue lessons on nutrition or physical activity as they use to give in their schoolclasses, but which are not combined in a theoretically grounded multi-component programme as provided to the intervention group. The control schools will be offered the opportunity to implement the multi-component programme for free after the experiment is finished. The school programmes of the control group (usual care) will be closely monitored in the process evaluation (see below).

Outcome criteria will be measured 4 times: T0 and T1 at respectively the beginning and end of the school year in group 6 of primary school; and T2 at the end of the school year in group 7; and finally T3 halfway the school year in group 8. Questionnaires will be administered in two ways at all measurement time points. Part of the outcome variables are included in a structured

interview questionnaire, to be conducted during the physical assessments of BMI and waist circumference. Other outcome variables are included in the written questionnaires that will be completed by the pupils in class under the guidance of teachers to achieve a maximum response rate.

Process evaluation

A process evaluation will be conducted to test whether the teachers of the study groups are presenting the programme as intended using questionnaires, registrations and observations. Moreover the childrens* and teachers' assessment of the attractiveness and usability of the multi-component programme will be established.

Intervention

The following components will be included in the overweight prevention programme for primary school children:

- a. promotion of healthy nutrition behaviours: promotion of fruit and vegetable intake, reduction of consumption of high fat and energy snacks and soft drinks, promotion of healthy breakfast
- b. reduction of inactivity i.e. of television watching, computer browsing and the use of computer games
- c. promotion of physical activity: promotion of school physical activities and participation in sports outside school hours.

The multi-component strategy will be built on promising existing Dutch school-based interventions that have been proven partially effective in a single delivery design or that are potentially effective but have not yet been evaluated. Some examples of existing potential projects in The Netherlands are interventions on nutrition education developed by the Netherlands Nutrition Centre (Voedingscentrum): *Smaaklessen* and *SchoolGruiten*. An intervention aimed at ecological change is the National Schoolbreakfast project. Examples of projects aiming at physical activity are *Kies voor hart en sport* developed by the Dutch Heart foundation, and *Lekker fit*, developed by the GGD Rotterdam Rijnmond. Where no usable interventions are available in the Dutch setting, we will select components from Planet Health or Eat Well and Keep Moving or other promising interventions. The intervention mapping (IM) protocol and the Dutch Healthy School Model will be used to give the the multi-component programme a sound foundation .

Change of the parents* parenting and health behaviours is not the primary aim of this programme. Of course we will adopt parent aimed school activities when the existing Dutch school-based interventions to be included in the programme use principles of parent involvement.

School teachers will give the nutrition education and physical activity lessons in their school classes. They will be trained to deliver the lessons as intended.

Study burden and risks

The child will participate in the evaluation study during three school years. A questionnaire will be filled out at four time points, taking half an hour per time point. Research assistants of the community health services will weigh the child and measure length and waist circumference. A 24-recall interview will be used to measure diet and physical activity behaviours. The physical measurements and interview will take 20 minutes per child per time point. All measurements will take place at the child's school.

No specific risks are associated with participation in the evaluation study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

As the programme is an intervention in the school class, all schoolclass children are invited to participate

Exclusion criteria

not applicable

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-08-2009
Enrollment:	1650
Type:	Actual

Ethics review

Approved WMO	
Date:	22-07-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL20823.058.07