Evaluation of the Dutch preventive Youth Health Care (YHC) Overweight Prevention-protocol and Overweight Detection-protocol among 5-year-old children in a cluster randomized trial

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This study contributes to the evaluation of the Detection- and Prevention-protocol, as applied by YHC to 5 to 6-year-olds.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30926

Source
ToetsingOnline

Brief title
'Be active, eat well'

Condition

- Other condition

Synonym
niet van toepassing

Health condition

niet van toepassing

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Children, Effectiveness, Overweight, Prevention

Outcome measures

Primary outcome

Evaluation of the prevention protocol:

· Change in waist circumference 24 months after the *PGO-5 to 6-year-olds* in children with *overweight not obesity* in the Intervention group relative to the Control group.

· Relative change in Body Mass Index 24 months after the *PGO-5-year-olds* in children with *overweight not obesity* in the Intervention group relative to the Control group.

Evaluation of the detection protocol:

· Predictive value of the labels *normal weight*, *overweight but not obesity*, and *obesity* at the *PGO-5-year-olds* according to the Detection-protocol for the presence of these labels at age 7 years.

Secondary outcome

Baseline measurements:

· Demographic and general characteristics;

· Data concerning pregnancy, birth weight, breastfeeding and medical history;

· Body mass index, and behaviors of parents themselves;

· Body mass index relative to sex and age specific norms and waist circumference

· Presence of overweight reducing and inducing behaviors (specific behaviors targeted in the intervention)

· Health-related quality of life

· Attitudes of parents regarding the specific health behaviors

· Baseline levels of indicators of negative side effects.

· Presence of label *overweight* (respectively *obesity*) according to Detection-protocol at age 7 (yes/no) (Bulk-Bunschoten et al, 2005);

· Levels of the five target overweight reducing and inducing behaviors (Promis questionnaires; van de Laar et al, 2006). For example: Change in average daily number of minutes watching TV, video, DVD or playing on a computer, 24 months after the *PGO-5-year-olds* in children with *overweight not obesity* in the Intervention group relative to the Control group (Doak et al., 2006; Renders et al., 2004);

- Health-related quality of life (CHQ-PF28; Raat et al, 2005);

- Attitudes of parents regarding the specific health behaviors (Promis questionnaires; van de Laar et al, 2006)

- Absence/presence of indicators of negative side effects (worry, stigmatization, lowered self-esteem, and development of relative underweight) (Doak et al., 2006).

Evaluation of the detection protocol:

- Sensitivity and specificity of the Detection-protocol at the *PGO-5-year-olds* for *overweight but not obesity*, and *obesity* at the age of 7 years, in the absence of weight-management interventions.
- Furthermore it will be assessed in how far this is modified by the five relevant target behaviors and by specific measures of body fatness other than Body Mass Index, such as waist circumference.

Measures regarding the Process evaluation:

- Adherence to the distinct elements of the interventions;
- Satisfaction of the parents with the interventions (modified Patient Satisfaction questionnaire) (Martinali et al, 2001);
- Understandability of program elements for parents (Promis questionnaire, van de Laar et al, 2006);
- Rating of possibility for application in day-to-day life by parents (van de Laar et al., 2006);
- Time investments of parents and YHC-professionals for YHC- visits;

Acceptability for the YHC-professionals of the interventions (van de Laar et al., 2006).

Measures regarding the Cost-effectiveness evaluation.

With regard to costs of the Prevention-protocol we will assess the costs of counseling visits, education of YHC-personnel, other program costs (e.g.

non-client related time investments of YHC-personnel with respect to program),

and time and travel costs of parents and children. Data on time investments,

expenditures and program costs will be collected by questionnaires among

YHC-personnel and parents, and from YHC administrative data sources.

Study description

Background summary

Overweight and obesity are main determinants of the ZonMw priority diseases. The prevalence of overweight and obesity among children has at least doubled in the past 25 years, especially in socially disadvantaged and specific ethnic subgroups. The current study proposes to evaluate a monitoring intervention and a counseling intervention in the setting of Dutch Youth Health Care (YHC), aiming at the prevention of obesity in childhood and at the prevention of overweight and obesity in adulthood. Dutch Youth Health Care (YHC) may contribute to the prevention of overweight and obesity by the recently developed YHC Overweight Detection-protocol (Signaleringsprotocol Overgewicht) and Prevention-protocol (Overbruggingsplan Overgewicht). The Detection-protocol identifies children with *overweight but no obesity*, and these children and their parents are offered the Prevention-protocol with three visits with a program of non-directing behavioral counseling to improve health behaviors and to reduce body fatness. These protocols have proven to be feasible and acceptable in the recent VUMC Promis study. The Prevention-protocol, however, has not yet been subjected to a rigorous effect evaluation.

Study objective

This study contributes to the evaluation of the Detection- and Prevention-protocol, as applied by YHC to 5 to 6-year-olds.

Study design

We propose a cluster-randomized trial with YHC-teams as unit of randomization. In the Intervention group both the Detection-protocol and the Prevention-protocol will be applied, while in the Control group the Detection-protocol will be applied in combination with *usual care*.

Intervention

The detection-protocol will be applied to all children participating in the

study. Subsequently, in the intervention group the prevention-protocol will be applied. In the control group the usual care of the Municipal Health Services will be applied.

Study burden and risks

The measures for weight, height and waist circumference will be applied to all children participating in the study. These measures will be repeated after 2 years of follow-up in a subgroup. Furthermore, the parents of a subgroup of children will receive a questionnaire to obtain additional information about lifestyle behaviors and determinants of lifestyle behaviours. After 1 and 2 years of follow-up this subgroup of parents will receive these questionnaires again.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)

Elderly (65 years and older)

Inclusion criteria

All 5-6 year old children in the second year of primary school during school year 2007/2008, which are invited for the 'PGO' will be invited to participate in the study.

Exclusion criteria

The children and their parents should be able to read and understand the basics of the Dutch language, because questionnaires and consults will be used in the study. Severely mentally or physically disabled children will be excluded. In these cases the YHC-professional should make a well-considered decision to invite or not invite these children and their parents to participate in the study.

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):	18-09-2007
Enrollment:	7200
Type:	Actual

Ethics review

Approved WMO

Date:	17-09-2007
Application type:	First submission
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
ISRCTN	ISRCTN04965410
CCMO	NL16845.078.07