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

Submission date	Recruitment status	[X] Prospectively registered
11/04/2007	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/04/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/09/2014	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR921

Study information

Scientific Title

'Be active, eat right' - Lifestyle, growth and health of children aged 4 to 7: Evaluation of an overweight detection protocol ('Signaleringsprotocol Overgewicht') and an overweight prevention protocol ('Overbruggingsplan Overgewicht') in Dutch Youth Health Care among children aged 4 to 7 and their parents in a cluster randomised trial

Study objectives
Current hypothesis as of 24/07/2008:
1. 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)
2. The prevention protocol applied to parents and their 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 body mass index (BMI) and waist circumference at age 7 compared to overweight children in the control group who receive usual care

Previous hypothesis:
It is hypothesised that the results of the evaluation of the overweight prevention-protocol and the overweight detection-protocol will be that they are effective and efficient protocols for overall use in the Youth-Health-Care (YHC).

On 24/07/2008 the following changes were made to this trial record:
1. The public trial title was changed from "'Be active, eat well', a healthy lifestyle for children at the age of five and six years: evaluation of the Dutch preventive Youth Health Care (YHC) overweight prevention-protocol and overweight detection-protocol among children at the age of five and six years in a cluster randomised trial".
2. The scientific trial title was added.
3. The anticipated trial start date has been updated from 01/09/2007.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Research Committee of Erasmus MC, University Medical Centre Rotterdam, 17/09/2007, ref: MEC-2007-163

Primary study design
Interventional

Study design
Randomised active-controlled parallel-group multicentre trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Youth Health Care and prevention of obesity in children

Interventions
Current interventions as of 24/07/2008:
The YHC teams in both the intervention and control groups will apply the detection protocol and

label children as "normal weight", "overweight" or "obese". The detection protocol entails measuring weight and height of the children, calculating their BMI and comparing it to international sex and age specific BMI cut-off points for overweight and obesity.

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-programme. The YHC professionals will assess whether the parents are motivated to participate in counselling to promote overweight preventing behaviours, and will make use of a motivational interview approach. The three additional structured lifestyle counselling visits are offered to parents in intervals of one, three and six months. During the visits, energy intake and expenditure diaries are used, which will be completed by the parents. The YHC professional and the parents together will draw up a family-oriented action plan aiming at promotion of physical activity and outdoor playing time, having breakfast daily, less sweet drinks and limitation of television and /or computer time.

The YHC teams in the control group will offer the parents of children with overweight usual care as offered by the YHC teams.

Previous interventions:
All YHC-teams will carry out the overweight detection-protocol and applying labels for 'normal weight', 'overweight, but no obesity' and 'overweight'. The YHC-teams in the intervention group will then offer the parents and children with 'overweight, but no obesity' the prevention-protocol, which includes a structured three-YHC-visits-program. The YHC-teams in the control group will offer the parents and children with 'overweight, but no obesity' the 'usual care', which includes the care the YHC-teams offer before implementing the prevention-protocol.

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Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Current primary outcome measures as of 28/07/2008:

Evaluation of the prevention protocol:
1. Body Mass Index (BMI), measured at baseline (age 5) and 24 months (age 7)
2. Waist circumference, measured at baseline (age 5) and 24 months (age 7)

Evaluation of the detection protocol:
1. Proportion of children labelled as "normal weight", "overweight" and "obesity" according to the detection protocol, measured at baseline (age 5) and 24 months (age 7)

Timepoints of measurement:
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)

Previous primary outcome measures:

Evaluation Prevention-protocol:
Change in body fat and relative change in Body Mass Index (BMI) two years after the 'PGO'* among children at the age of five or six years, in children with 'overweight but no obesity' in the Intervention group relative to the Control group.

Time-point measurements:
PGO: September 2007 -June 2008
Repetition of measurements: September 2009 - June 2010

Evaluation Detection-protocol:
Predictive value of the labels 'normal weight', 'overweight but not obesity', and 'obesity' at the 'PGO' among children at the age of five or six years, according to the Detection-protocol for the presence of these labels at the age of about seven years, in the absence of weight-management interventions.

Time-point measurements:
PGO: September 2007 - June 2008
Repetition of detection: September 2009 - June 2010

*The 'PGO' is a contact moment at the Municipal Health Service (GGD'en) where a specialised physician carries out a preventive health check on all children in the second year of elementary school.

Key secondary outcome(s)

Current secondary outcome measures as of 28/07/2008:
Evaluation of the prevention protocol:
1. Levels of the four target overweight-reducing and overweight-inducing behaviours, i.e. being physically active, eating breakfast daily, drinking sweet beverages and watching TV or playing on a computer, measured at baseline (age 5), 12 months (age 6) and 24 months (age 7)
2. Health-related quality of life, measured at baseline (age 5), 12 months (age 6) and 24 months (age 7)
3. Attitudes of parents regarding the four target behaviours mentioned above (see 1), measured at baseline (age 5), 12 months (age 6) and 24 months (age 7)
4. Absence or presence of indicators of negative side effects, i.e. worry, stigmatisation, lowered self-esteem and development of relative underweight, measured at baseline (age 5) and 24 months (age 7)

Evaluation of the detection protocol:
1. Sensitivity and specificity of the labels "normal weight", "overweight" and "obesity" according to the detection protocol, measured at baseline (age 5) and 24 months (age 7)

Timepoints of measurement:
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)

Previous secondary outcome measures:
1. Waist circumference
Time-point measurements:
PGO: September 2007 - June 2008
Repetition of measurements: September 2009 - June 2010
2. Levels of five target overweight reducing and inducing behaviours
3. Health-related quality of life
4. Attitudes of parents regarding the specific health behaviours
5. Absence/presence of indicators of negative side effects (worry, stigmatisation, lowered self-esteem, and development of relative underweight)
Time-point measurements:
PGO: September 2007 - June 2008
First follow-up measurement: September 2008 - June 2009
Second follow-up measurement: September 2009 - June 2010

Completion date
01/09/2010

Eligibility

Key inclusion criteria
Current inclusion criteria as of 24/07/2008:
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.

Previous inclusion criteria:
All children in the second year of elementary school who are invited by the municipal health services to visit the YHC-team will be included in the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Current exclusion criteria as of 30/07/2008:
For the prevention protocol and the questionnaires used in the study, parents without basic Dutch language skills will be excluded.

Previous exclusion criteria:
In the study questionnaires and counselling will be used. Therefore it is necessary that parents are able to understand and communicate in Dutch. Furthermore it is possible that in some cases of children and parents who visit the YHC-teams, weight and potential overweight are not high priority factors and other factors are more important to discuss and pay attention to.

Date of first enrolment
18/09/2007

Date of final enrolment
01/09/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Centre, Room AE-131
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Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	31/05/2013		Yes	No
Results article	results	21/01/2014		Yes	No
Protocol article	protocol	08/06/2009		Yes	No