Pilot study to test an environmental intervention aimed at the prevention of excessive weight gain in 4-year old overweight children.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33602

Source
ToetsingOnline

Brief title
Pilot environmental intervention children with overweight

Condition

- Other condition

Synonym
adiposity, obesity, Overweight

Health condition

overgewicht

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Zon MW

Intervention

Keyword: Children, Environment, Intervention, Overweight

Outcome measures

Primary outcome

Primary study endpoint is the extent to which the intervention is applicable to the needs and the motivation of the parents.

Secondary outcome

Secondary parameters are the extent to which the intervention is feasible within the organizational structure and the perceived advantages and disadvantages of the intervention according the YHC physician and the health educator.

Study description

Background summary

Overweight and obesity are already prevalent in 4-year-old children. Obesity-inducing behaviours in young children have been found to track throughout the life span. Acknowledging the a lack of effective interventions aimed at preschool children, the current study aims at executing a pilot study in which a systematically developed environmental intervention aimed at the parents of 4-year-old children is tested.

Study objective

The main objective of the current study is to investigate to what extent the intervention is applicable to the needs and motivation of the target group

(parents). In addition, it is tested whether the intervention is feasible for primary care Youth Health Care (YHC) professionals to incorporate in their daily practice.

Study design

The design of the current study is a pretest posttest observational design.

Intervention

The intervention will take 13 weeks, consisting of a 40-60 minute home visit, five 90-minute parental group training sessions, a second home visit and another four parental group training sessions. During the home visits, a specially trained health educator will identify obesity-inducing environmental factors in the home setting together with the parents, using a structured observation form. The completed grid will be the starting point for the group sessions. These group training sessions are designed according to the principles of Positive Parenting Program (Triple P), an evidence-based preventively oriented parenting and family support strategy, based on social learning principles. Thus, the physical home environment will be made less obesogenic and the parents are guided to develop and maintain effective parenting practices to change the obesogenity of the environment.

Study burden and risks

The intervention which the parents of the children receive will take 13 weeks and consists of two home visits, six parental group training sessions, and three telephone sessions. Furthermore, the body composition of the children (i.e. length, weight, waist circumference, skinfiolds) is measured for their anthropometric variables and the children are asked to wear an Actigraph accelerometer for one week at baseline and at 14 weeks follow up. The parents of the children are asked to fill out a questionnaire at baseline and at 14 weeks follow-up and to participate in a focus group at the end of the intervention. Participation in the current study is voluntary and is without any risks.

Contacts

Public
Universiteit Maastricht

P. Debijeplein 1
6229 HA Maastricht
Nederland

Scientific
Universiteit Maastricht

P. Debijeplein 1
6229 HA Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Parents of children aged 3 years, 9 months who are labeled by the YHC physician as overweight, but not obese.

Exclusion criteria

Parents from children with an organic cause of their overweight are excluded from the study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2009
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	11-02-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL25103.068.08