

Onderzoek naar een programma om overmatige gewichtstoename bij 4- t/m 8-jarige kinderen tegen te gaan.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23608

Source

NTR

Brief title

GO4fit

Health condition

overweight, obesity

Sponsors and support

Primary sponsor: Nutrition and Toxicology Research Institute Maastricht (NUTRIM), Maastricht University

Source(s) of monetary or material Support: Netherlands Organization for Health Research and Development (ZonMW)

Intervention

Outcome measures

Primary outcome

The main study parameter is children's body composition, determined by BMI z-score

(calculated by weight, height, age and gender), waist circumference, and fat mass (assessed by biceps and triceps skinfold and deuterium dilution).

Secondary outcome

1. Children's lifestyle (snacking behaviour, soft-drink consumption, fruit-and vegetable consumption and physical activity);
2. Parental body composition (BMI, parental fat mass);
3. Parental physical activity level;
4. Parenting self-efficacy and parenting style.

Study description

Background summary

Rationale:

Overweight and obesity are already prevalent in 4- till 8-year-old children. Obesity-inducing behaviours in young children have been found to track throughout the life span. Acknowledging the lack of effective interventions aimed at preschool children, the current study aims at executing an effectiveness study in which a lifestyle intervention aimed at the parents of 4- till 8-year-old children is tested.

Objective:

The main objective is to evaluate the effectiveness of Lifestyle Triple P.

Study design:

The design of the current study is a Randomized Controlled Trial (RCT).

Study population:

The research population consists of 288 participants (96 overweight and obese 4- till 8-year-old children and their parents).

Intervention: The lifestyle intervention, called Lifestyle Positive Parenting Program (Lifestyle Triple P), is aimed at parents of overweight and obese children. The control condition receives two information leaflets, a Time Machine and a web-based tailored feedback about providing a good parental example for your child regarding diet and physical activity.

Main study parameters/endpoints:

The main study parameter is children's body composition, determined by BMI z-score (calculated by weight, height, age and gender), waist circumference, and fat mass (assessed by biceps and triceps skinfold and deuterium dilution). Secondary study parameters are children's lifestyle (snacking behaviour, soft-drink consumption, fruit-and vegetable consumption and physical activity), parental body composition (BMI, parental fat mass), parental physical activity level, parenting self-efficacy and parenting style.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The intervention which the parents of the children receive will take 14 weeks and consists of ten parental group training sessions, and four individual telephone sessions. Furthermore, the body composition of the children and parents (i.e. length, weight, waist circumference, biceps and triceps skinfolds) is measured, children and their parents are asked to wear an Actigraph accelerometer for one week and parents are asked to fill out a questionnaire at baseline, 14 weeks follow-up and 12 months follow-up. Additionally, children's fat mass is also estimated at baseline and 12 months follow-up using deuterium, the gold standard. Participation in the current study is voluntary and without any risks.

Study objective

Overweight and obesity are already prevalent in 4- till 8-year-old children. Obesity-inducing behaviours in young children have been found to track throughout the life span. Acknowledging the lack of effective interventions aimed at preschool children, the current study aims at executing an effectiveness study in which a lifestyle intervention aimed at the parents of 4- till 8-year-old children is tested.

Study design

Baseline: Children's body composition, determined by BMI z-score (calculated by weight, height, age and gender), waist circumference, fat mass (assessed by biceps and triceps skinfold and deuterium dilution), children's lifestyle (snacking behaviour, soft-drink consumption, fruit-and vegetable consumption and physical activity), parental body composition (BMI, parental fat mass), parental physical activity level, parenting self-efficacy and parenting style.

14-weeks follow-up: Children's body composition, determined by BMI z-score (calculated by weight, height, age and gender), waist circumference, fat mass (assessed by biceps and triceps skinfold), children's lifestyle (snacking behaviour, soft-drink consumption, fruit-and vegetable consumption and physical activity), parental body composition (BMI, parental fat mass), parental physical activity level, parenting self-efficacy and parenting style.

12-months follow-up: Children's body composition, determined by BMI z-score (calculated by weight, height, age and gender), waist circumference, fat mass (assessed by biceps and triceps skinfold and deuterium dilution), children's lifestyle (snacking behaviour, soft-drink consumption, fruit-and vegetable consumption and physical activity), parental body composition (BMI, parental fat mass), parental physical activity level, parenting self-efficacy and parenting style.

Intervention

The lifestyle intervention, called Lifestyle Positive Parenting Program (Lifestyle Triple P), is aimed at parents of overweight and obese children. The intervention will take 14 weeks, consisting of eight weekly 120-minute parental group training sessions, two individual telephone sessions, one parental group training sessions, two individual telephone sessions and a final parental group training session. Triple P is an evidence-based preventively oriented parenting and family support strategy, based on social learning principles. Active skills training methods are employed to help parents acquire new knowledge and skills.

The control condition receives two information leaflets (one about healthy nutrition and physical activity, and one about positive parenting), a Time Machine (an electronic screen time manager) and a web-based tailored feedback about providing a good parental example for your child regarding diet and physical activity.

Contacts

Public

P.O. Box 616
Sanne Gerards
Maastricht University, Department of Health Promotion
Maastricht 6200 MD
The Netherlands
+31 (0)43 3882439

Scientific

P.O. Box 616
Sanne Gerards

Eligibility criteria

Inclusion criteria

Parents are eligible for inclusion when:

1. Their child is aged 4 till 8 years old;
2. When their child is labelled as overweight or obese after calculating the BMI and by using the international cut-off points of Cole et al. (14) (which are based on six large nationally representative cross sectional surveys on growth including the Netherlands).

Parents who agree to participate in the study, and both sign for informed consent, are included in the study.

Exclusion criteria

Parents of children who have a medical cause for their overweight and parents who both do not speak the Dutch language are excluded from the current study.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 01-09-2010
Enrollment: 96
Type: Anticipated

Ethics review

Positive opinion
Date: 04-10-2010
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	NL2285
NTR-old	NTR2555
Other	ZonMW : 120520009
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

6 - Onderzoek naar een programma om overmatige gewichtstoename bij 4- t/m 8-jarige k ... 11-05-2025

N/A