

GECKO Outpatients Clinic

No registrations found.

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

Summary

ID

NL-OMON24863

Source

NTR

Health condition

overweight, obesity

Sponsors and support

Primary sponsor: University of Groningen

Source(s) of monetary or material Support: A.S. Watson (Europe) Holding BV
Menzis Zorgverzekeraar

Intervention

Outcome measures

Primary outcome

Difference in progression of BMI between both groups

Secondary outcome

Dietary intake, physical activity, behavioral modification, body composition, fat distribution, metabolic syndrome, insulin resistance, blood lipid profile, inflammatory markers, quality of life

Study description

Background summary

Childhood obesity is increasing worldwide. Also in the Netherlands the prevalence of overweight and obese children has expanded. Very alarming is the rise in prevalence among very young children. Obesity treatment in children is difficult. No consensus has been reached on the best intervention method. Although beneficial effects of multidisciplinary treatment in older children and adolescents have been demonstrated, little is known about treating younger children.

The aim of this study is to evaluate effects of a multidisciplinary intervention in overweight children aged 3-6 years old.

The study will be a randomized controlled clinical trial. Overweight children, 3-6 years old living in the provinces of Groningen, Drenthe and Friesland will be included in the study. Overweight defined according to the international cut off points for overweight. Children are randomized into usual care or an intense multidisciplinary treatment program, collaboratively given by a pediatrician, dietician, physiotherapist and behavioral therapist. Evening sessions will be held to augment parent's knowledge and understanding of healthy eating and activity patterns, obesity and its health risks. The intervention period runs 4 months, mean follow up afterwards will be 12 months.

Primary outcome in the study is the change in body mass index. Secondary outcomes include changes in body composition, fat distribution, physical activity, dietary intake, behavior modification, quality of life, metabolic syndrome, and obesity related inflammatory markers and hormones. A study population of 180 children should provide 80% power to detect a difference of 2 units kg/m² in BMI. Analysis will be by intention-to-treat.

Study objective

Does a multidisciplinary treatment program consisting of dietary advice, life style activity and psychological counseling, aimed at preschool overweight children , as well as their parents, influence the Body Mass Index?

Intervention

So far there haven't been a lot of studies on the effects of treatment aimed at weight reduction of overweight and obese pre-school children. There is clear evidence, however, that the combination of cognitive behavioral therapy, dietary guidance and lifestyle activity change is very effective for weight reduction in older children.

Interventions will be divided in two groups; the intervention and the usual care group.

The intervention group will receive a three months multidisciplinary treatment program.

The dietary intervention will consist of a normocaloric diet; based on the required daily intake for this age group. Thus securing sufficient normal growth. In six meetings parents and child will receive education and advice to ameliorate their eating behaviors.

The exercise program will focus on an active lifestyle. Children and parents will be encouraged to reduce sedentary activities. Also a physiotherapist will guide them once a

week in a group training (10 children per group) session. The children will perform physical activity that mimics the type and intensity of elementary school exercise. These sessions will last one hour. The parents will be asked to add on an extra 60 minutes of physical activity of their own once per week, building up to every day according to the Dutch Standard of Healthy Activities.

Parents will also receive six sessions of behavioral therapy. In these sessions they will learn to be a healthy role model, work with feasible goals and healthy rewards, sticker charts to motivate the children and keep track of the progress, change family attitudes towards healthy eating and physical activity, practical ways to remove unhealthy food triggers and the difference between hunger and cravings. These sessions are group sessions. To diminish the burden of appointments these sessions take place in the evening.

In the usual care group a pediatrician will follow up the child and its parents. In a period of 3 months they will be seen three times, for 30-60 minutes. They will receive information on healthy eating behavior and instructions to perform physical activity 1x per week for 60 minutes on their own, building up to every day according to the Dutch Standard of Healthy Activities.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children aged 3 to 6 years old, who are overweight - overweight defined by BMI above the international cut off points for overweight by Cole et al.;
2. Living in the Provinces of Groningen, Drenthe or Friesland.

Exclusion criteria

1. Children with mental retardation;
2. Severe behavioral problems;
3. Other criteria interfering with participation (for example not speaking Dutch);
4. Children with obesity due to known medical causes or eating disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	10-10-2006
Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion	
Date:	16-01-2007
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	NL858
NTR-old	NTR872
Other	: N/A
ISRCTN	ISRCTN47185691

Study results

Summary results

N/A