The effect evaluation of a multidiscipinary treatment in children with obesity.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON30355

Source
ToetsingOnline

Brief title
Childhood obesity

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)
- Lifestyle issues

Synonym
extreme overweight, obesity

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: regionale zorgverzekeraars en unrestricted educational grant

Intervention

Keyword: childhood obesity, gastrointestinal hormones, metabolic abnormalities, multidisciplinary treatment

Outcome measures

Primary outcome

1. Do children/adolescents with obesity have a significant decrease in BMI (>

0.6 BMI-sds) after 3 months of intensive treatment compared to

children/adolescents who received a standard treatment (increased physical

activity and nutrition advice) ?

Secondary outcome

1. Do children/adolescents with obesity have a significant beneficial effect

after three months intensive treatment compared to children/adolescents who

received a standard treatment (increased physical activity and nutrition

advice) on sum of skinfolds, insulin sensitivity, metabolic syndrome,

gastrointestinal hormones, cardiovascular fitness, and quality of life?

2. Will the effects of three months intensive treatment of children/adolescents

with obesity be maintained after 12 and 24 months of follow-up?

3. Are intervention and control group homogeneous with regard to relevant

genetic background?

4. Is parent education a predictive variable on the degree of obesity of

children/adolescents?

Study description

Background summary

The prevalence of childhood overweight and obesity has increased rapidly during the last two decades in the Netherlands. Genetic as well as environmental factors have contributed to this trend. Genetic variations in the insulin receptor substrate-1 gene (IRS-1) and in the glucocorticoid receptor (GR) are associated with the degree of obesity and insulin resistance. Also several gastrointestinal hormones, responsible for appetite and food intake, are impaired in overweight and obese subjects. Parental overweight or obesity and low social economic status or education are risk factors for childhood overweight or obesity. Childhood overweight or obesity affects self-esteem and has negative consequences on cognitive and social development. Overweight increases the risk for developing cardiovascular complications, diabetes mellitus type 2, metabolic syndrome, joint problems, and psychosocial problems. Because of the increasing prevalence of childhood overweight and obesity and the impact on individuals and society, prevention of overweight and obesity is of high importance.

Study objective

The main parameter of the study is evaluation and effectiveness of the treatment program on Body Mass Index (BMI) (as defined by Cole et al) compared to a standard intervention (increased physical activity and nutrient advice). Also the effectiveness of the treatment compared to the standard intervention, on sum of skinfolds, insulin sensitivity, metabolic syndrome, gastrointestinal hormones, cardiovascular fitness, and quality of life will be studied.

Study design

An open randomised controlled intervention study.
Newly presented children/adolescents with obesity will be physically examined. All children eligible for the study and their parents will be informed by the paediatrician and will be asked to read the information letter before giving their informed consent. After dividing the participants in a children's group (8-12 years) and an adolescent group (13-17 years) stratification (on sex and ethnicity) and randomisation will take place. An experienced person blinded for the study design will measure weight and height (main study parameter).

Intervention

The intervention group is offered 7 group meetings of 2 1/2 hour and the parents are offered 4 separate parent meetings en 1 meeting together with the children/adolescents. Main topics are education on nutrition, physical activity

and improvement of self-esteem.
Children/adolescents in the control group are given a standard treatment (increased physical activity and nutrition advice). They are offered to participate in the treatment program after the 12 months study period.

Study burden and risks

For evaluation of short-term, midterm and long-term effects of the treatment, measurements will be taken at the beginning of the treatment, after 3 months of treatment and after 12 and 24 (intervention group only) months of follow-up. During these three (four) visits the following procedures will be performed: pysical examination, metabolic screening, cardiovascular fitness evaluation, mixed meal test and quality of life questionnaires.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

* age 8-17 years (at beginning)
* Obesity BMI values difined by Cole et al.
* Childeren/adolescents presented to the paediatrician

Exclusion criteria

* Insufficient knowledge/understanding of the Dutch language;
* Children/adolescents following special education;
* Serious co-morbidity
* Obesity caused by a syndrome (like Prader Willi, Laurence-Moon-Biedl);
* Endocrine cause of obesity (like hypothyreoidy, Cushing);
* Obesity caused by medication (like high dose of glucocorticoids);
* Parents and children/adolescents not willing to invest 40 hours in the treatment;
* Children/adolescents with diabetes mellitus;
* Children/adolescents who already followed a multidisciplinary treatment; including psychological treatment and intensive parent involvement.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-03-2007
Enrollment:	120

Type:	Actual

Ethics review

Approved WMO Date:	13-02-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL14974.098.06