The effect of a 12-week multidisciplinary treatment on the vascular function in obese children in the age of 8-17 years.

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1) To examine the effect of a 12-week multidisciplinary treatment on endothelial function, intima-media thickness and blood cholesterol in obese children (8-17 years).2) Investigate the changes in vascular function in obese children (8-17 years).

Ethical review	Approved WMO
Status	Pending
Health condition type	Appetite and general nutritional disorders
Study type	Observational non invasive

Summary

ID

NL-OMON30222

Source ToetsingOnline

Brief title Treatment of obesity in children (8-17 years)

Condition

• Appetite and general nutritional disorders

Synonym obesity

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud Source(s) of monetary or material Support: Ministerie van OC&W

1 - The effect of a 12-week multidisciplinary treatment on the vascular function in ... 4-05-2025

Intervention

Keyword: Children, Endothelial function, Obesity, Treatment

Outcome measures

Primary outcome

Endothelial function of the brachial and superficial femoral artery

Intima-media thickness of the carotid and superficial femoral artery

Secondary outcome

Body fat percentage, weight, blood cholesterol (and high-density lipoproteins,

low-density lipoproteins and triglycerides)

Study description

Background summary

The past two decades, the prevalence of obesity in children in USA, but also in The Netherlands, has doubled. This increase in prevalence of obesity in children emphasizes the importance of primary prevention of obesity in children. Moreover, childhood obesity is associated with several risk factors for later heart disease, diabetes, other chronic diseases and osteoartrosis.

Several previous studies examined the effect of childhood obesity on the vascular function. It is found that even obese children at the age of 8-10 demonstrate endothelial dysfunction (which is a precursor to atheroslcerotic diseases and is present in subjects with cardiovascular disease and risk factors). In addition, childhood obesity leads to structural changes in the arterial wall (increased intima-media thickness), increased levels of homosyteine and a hyperviscosity of the blood. These changes are associated with an increased risk of cardiovascular disease.

Primary prevention may be the key to decreasing obesity and limiting its societal impact. Physical inactivity and life style changes (food ingestion) are the most important factors that should be altered when preventing (childhood) obesity. Especially starting an intervention at a young age may be beneficial since it has been proposed that encouraging the development of physical activity habits in children helps establish patterns that continue

into their adulthood.

Study objective

1) To examine the effect of a 12-week multidisciplinary treatment on endothelial function, intima-media thickness and blood cholesterol in obese children (8-17 years).

2) Investigate the changes in vascular function in obese children (8-17 years).

Study design

Observational pilotstudy in which a 12-week multidisciplinary treatment is applied as an intervention.

Study burden and risks

All participants start with a non-invasive and minimally challenging assessment of the vascular characteristics. First, echo-Doppler measurements are used to examine baseline blood flow, intima-media thickness, arterial lumen and endothelial function of 3 major conduit arteries (carotid, brachial, superficial femoral artery). These assessments are not harmful and no risks are associated. Several years of experience is present at the department of Physiology regarding these experiments. In the past, these tests were used to examine a broad group of subjects (elderly, spinal cord injury, metabolic syndrome, obesity in adolescents and middle-aged, endurance athletes). The only possible burden for the participants is the collection of capillary blood (optional test). However, this collection is without any risks.

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

Aged 8-17 years Healthy Obesity (based on the international guidelines for obesity in children, see figure 1 in appendix 1) Signed informed consent

Exclusion criteria

Metabolic, muscular or neurologic disease Specific syndroms in which obesity is an inclusion criterium (Prader-Willi syndrom)

Study design

Design

Study type: Observational non invasiveMasking:Open (masking not used)Control:UncontrolledPrimary purpose:Prevention

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	15
Туре:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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 CCMO ID NL14335.091.06