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The effect of lifestyle treatment on childhood obesity

Submission date 06/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/07/2010	**Overall study status** Completed	
Last Edited 21/09/2011	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06-091

Study information

Scientific Title

A randomised controlled trial evaluating the effect of family-based multidisciplinary cognitive behavioural treatment in children with obesity

Acronym
Haagse Maatjes

Study objectives
During the last three decades the prevalence of childhood obesity has increased dramatically in western countries, including the Netherlands. The rapidly increasing prevalence of childhood obesity seen during the last few decades, is mostly the result of an increased food consumption and a change from a more physically active lifestyle to a more sedentary one. The consequence of the increased prevalence of childhood obesity is the earlier appearance of co-morbidities.

The primary aim of this study is the effect evaluation of a family-based multidisciplinary cognitive behavioural treatment on obesity (expressed as body mass index [BMI]-standard deviation score [SDS]) compared to standard care (advice on increased physical activity and dietary changes) in children with obesity. The secondary aim of the study was to investigate the effect of this treatment on changes in waist circumference, insulin sensitivity, inflammation, secretion of gastrointestinal hormones and changes in physical fitness and quality of life, compared to standard care. Furthermore, we aimed at assessing the long-term effects and possible predictive factors for response treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Dutch National Medical Ethical Committee approved on the 13th of February 2007 (ref: METC-nr. 06-091)

Study design
Longitudinal single centre single blind randomised clinical trial, with stratification for gender and ethnicity

Primary study design
Interventional

Secondary study design
Other

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Childhood obesity

Interventions
The cognitive behaviour treatment program takes two years, with an intensive phase of three monthsat the beginning, followed by booster sessions. In the screening phase the children with their parents were seen at two separate occasions individually by a dietitian, a child-physiotherapist, a child-psychologist and a social worker. In this way individual family situations which could interfere with the treatment are evaluated and expectations of the program are checked. During the intensive phase of the program the experimental group is offered 7 group meetings of 2 1/2 hours and the parents are offered 5 separate parent meetings and 1 meeting together with the children. The control group is given an initial physical activity and nutritional advice. The control group is offered to participate in the treatment after 12 months. The normal weight control group is measured only once. A person blinded for the study design measures weight and height at baseline.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Do children (8-17 yr.) with obesity show a significant decrease (> 0.5 BMI-SDS) in BMI (as defined by Cole et al.[2]) after 3 months of intensive treatment compared to children who were given advice on increased physical activity and dietary changes?

Secondary outcome measures
1. Do children with obesity have a significantly more beneficial effect of 3 months intensive treatment compared to standard care on changes in waist circumference, insulin sensitivity, secretion of gastrointestinal hormones, cardiovascular fitness and quality of life?
2. Will the hypothesized beneficial effects of 3 months intensive treatment in children with obesity persist after 12 and 24 months of follow-up?
3. Are the genetic background of the children, the level of parental education, the social economic status or the ethnicity predictive variables for the degree of obesity in these children, and for the success of treatment?

Overall study start date
13/03/2007

Completion date
30/09/2010

Eligibility

Key inclusion criteria
1. Age 8-17 years (at baseline)
2. Obesity based on BMI values defined by Cole et al.
3. Children/ adolescents presented to the paediatrician
4. Written informed consent from parents and children

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
17 Years

Sex
Both

Target number of participants
35 per group, 70 in total

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

Date of first enrolment
13/03/2007

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Sportlaan 600
the Hague
Netherlands
2566 JM

Sponsor information

Organisation
Haga Teaching Hospital (HagaZiekenhuis) (Netherlands)

Sponsor details
c/o E.C.A.M. Houdijk
Sportlaan 600
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03q4p1y48

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Juliana Children's Hospital, HagaHospital (Netherlands) - unrestricted educational grand

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/05/2011		Yes	No