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The effectiveness of multidisciplinary treatment in young overweight children: GECKO outpatients clinic, a randomised controlled trial

Submission date
08/02/2007

Recruitment status
No longer recruiting

Registration date
08/02/2007

Overall study status
Completed

Last Edited
31/10/2012

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
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.

Hypothesis:
Does a multidisciplinary treatment program consisting of dietary advice, life style activity and psychological counselling, aimed at preschool overweight children, as well as their parents, influence the progression of Body Mass Index (BMI)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medisch Ethische Toetsingscommissie Universitair Medisch Centrum Groningen, 19th January 2006 (amendment approved 2nd February 2007), ref: METc 2005/261

Study design
Randomised active-controlled parallel group single-blind trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity, Overweight

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

Intervention:
1. The intervention group will receive a three months multidisciplinary treatment program
2. 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 behaviours
3. The exercise program will focus on an active lifestyle. Children and parents will be encouraged to reduce sedentary activities. A physiotherapist will guide them once a week in a group training (ten 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
4. Parents will also receive six sessions of behavioural 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.

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

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Difference in progression of BMI between both groups.

Key secondary outcome(s))
1. Dietary intake
2. Physical activity
3. Behavioural modification
4. Body composition
5. Fat distribution
6. Metabolic syndrome
7. Insulin resistance
8. Blood lipid profile
9. Inflammatory markers
10. Quality of life

Completion date
01/08/2009

Eligibility

Key inclusion criteria
1. Children aged three to six years old, who are 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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
6 years

Sex
All

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

Date of first enrolment
10/10/2006

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
Universitair Medisch Centrum Groningen (UMCG)
Groningen
Netherlands
9700 RB

Sponsor information

Organisation
University Medical Centre Groningen (UMCG) (The Netherlands)

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type

Industry

Funder Name
Menzis Zorgverzekeraar (The Netherlands)

Funder Name
A.S. Watson (Europe) Holding BV (The Netherlands)

Results and Publications

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?
Results article	results	01/12/2012		Yes	No