

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

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<b>Registration date</b> 08/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 31/10/2012	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr H Oude Luttikhuis

### Contact details

Universitair Medisch Centrum Groningen (UMCG)  
Beatrix Kinderkliniek  
P.O. Box 30001  
Groningen  
Netherlands  
9700 RB  
+31 (0)50 361 0585  
[h.oudeluttikhuis@bkk.umcg.nl](mailto:h.oudeluttikhuis@bkk.umcg.nl)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Treatment

### Participant information sheet

### 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 measure**

Difference in progression of BMI between both groups.

**Secondary outcome measures**

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

**Overall study start date**

10/10/2006

**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

## Age group

Child

## Lower age limit

3 Years

## Upper age limit

6 Years

## Sex

Both

## Target number of participants

180

## 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)

## Sponsor details

Beatrix Children's Hospital  
P.O. Box 30001  
Groningen  
Netherlands  
9700 RB

## Sponsor type

Hospital/treatment centre

## Website

<http://www.rug.nl/umcg/index?lang=en>

## 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

## 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?
<a href="#">Results article</a>	results	01/12/2012		Yes	No