

A Lifestyle Intervention Program in Children with Obesity (LIPCO)

Submission date 03/01/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/02/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 31/07/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Childhood obesity has become a common disease since the 1980s. The aim of this study was to implement and compare two different 12-month lifestyle treatment protocols for 10-year old children with obesity in primary pediatric care.

Who can participate?

Children aged 10 years with obesity.

What does the study involve?

Children were referred from school health care and were randomly allocated to one of the two programs. The children undergoing treatment were assessed medically at the start of the study and after 1 year. Measurements of weight, height, waist circumference, blood pressure and biological markers in the blood were carried out at assessments. For comparison, normal weight and overweight children were also studied in parallel, but no intervention took place in these children. A waiting list control group of children with obesity, not receiving treatment, were also used for comparison.

What are the possible benefits and risks of participating?

Not provided at time of registration.

Where is the study run from?

The study was performed in the region of Västra Götaland in Sweden at four pediatric outpatient wards.

When is the study starting and how long is it expected to run for?

The study ran from April 2004 to February 2007.

Who is funding the study?

Healthcare Authority, Västra Götaland (Sweden).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A one-year lifestyle intervention program emphasizing physical activity versus a conventional program in 10 year old children with obesity: a randomised controlled trial

Acronym
LIPCO

Study objectives
Putting an emphasis on physical activity in the treatment of children with obesity will result in a more favorable 1 year outcomes of body mass index (BMI), waist circumference, and metabolic markers than a protocol without such components.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethical Committee of Göteborg University, 09/12/2003, ref: Ö348-03

Study design

Multicenter randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Obesity

Interventions

At each of the four centres, nurses and dieticians met children and parents 12 times during 1 year.

Both arms had most elements in common. The children were included and randomized to either treatment arm consecutively. They were examined immediately before and directly after the intervention by a pediatrician. Special attention was given to anthropometric and blood pressure measurements, blood sampling for markers of the metabolic syndrome and a detailed parental questionnaire. All had 12 one-hour visits during a 12-month period, when parents and children met pediatric nurses four times or dieticians four times.

The remaining four visits were planned to differ for the two arms: in one a physiotherapist met the child and its parents and had the task to stimulate an increase in daily physical activity. Pedometers, reduction-of-TV-viewing-curricula and special fun diaries, phone reminders and support at follow-up visits were used to emphasize/stimulate physical activity in the family lifestyle. In the other arm, the pediatric nurse had the corresponding four visits using 'conventional' methods.

Motivational interviewing and lifestyle change protocols where cognitive behavior techniques were used and common methods for all personnel in both arms.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

BMI - z score

Secondary outcome measures

1. Waist circumference
2. Homeostatic Model Assessment (HOMA) score
3. Lipids and other markers in blood

Measured 4-5 years after the start of the treatment

Overall study start date

01/04/2004

Completion date

01/02/2007

Eligibility

Key inclusion criteria

1. Children aged 10 years with obesity defined by the International Obesity Task Force (IOTF) cut-offs
2. Informed consent given from the parents of all patients

Participant type(s)

Patient

Age group

Child

Lower age limit

10 Years

Upper age limit

10 Years

Sex

Both

Target number of participants

25 in each group

Key exclusion criteria

Syndromal obesity

Date of first enrolment

01/04/2004

Date of final enrolment

01/02/2007

Locations

Countries of recruitment

Sweden

Study participating centre

The Queen Silvia Children's Hospital

Göteborg

Sweden

SE 41685

Sponsor information

Organisation

Health Authority, Västra Götaland (Sweden)

Sponsor details

Västra Götalandsregionen

Box 1091

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Sponsor type

Government

Website

<http://www.vgregion.se/en/>

ROR

<https://ror.org/00a4x6777>

Funder(s)

Funder type

Government

Funder Name

Healthcare Authority, Västra Götaland (Sweden)

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?
Results article	results	01/06/2013		Yes	No