

Effects of the THAO-Child Health intervention program on the prevention of childhood obesity - the POIBC study

Submission date 22/07/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 01/08/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/10/2024	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The increasing rate of childhood obesity is a serious worldwide public health problem. Community-based intervention programs are a holistic approach to prevent childhood obesity. We want to find out the effect of a community-based intervention program called the THAO-Child Health program on weight development and lifestyle of children and their families.

Who can participate?

This study aims to recruit 2140 boys and girls aged 8 to 10 years (4th and 5th grade of elementary school).

What does the study involve?

The four cities where the programme will be implemented will be randomly allocated to two groups. The THAO-Child Health Program will be implemented in the cities of Terrassa and Sant Boi de Llobregat. The other two cities, Molins de Rei and Gavà, will act as the control group and will not receive the THAO-Child Health Program. Repeated measures of dietary intake and behaviour, physical activity, sleep quality, quality of life, and changes in the body composition will be performed among all participating children. Additionally, parental social and demographic changes, diet quality, and physical activity will be recorded.

What are the possible benefits and risks of the participants?

Participants in the intervention group may benefit from effective weight management and lifestyle improvements.

Where is the study run from?

The study is run from four Catalan cities in Spain (Terrassa, Sant Boi de Llobregat, Molins de Rei, and Gavà).

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

From January 2012 to December 2014.

Who is funding the study?
Institute of Health Carlos III (Instituto de Salud Carlos III), Feder, Madrid (Spain).

Who is the main contact?
Dr Helmut Schröder
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Instituto de Salud Carlos III FEDER, PI11/01900.

Study information

Scientific Title
Effects of a lifestyle intervention on the prevention of childhood obesity: a community-based model - the POIBC study

Acronym
POIBC

Study objectives
The THAO-Child Health intervention program favourably affects weight management, reduces incidence of obesity, and improves lifestyle.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee - CEIC-PSMAR, Barcelona, Spain, 21/11/2011, ref: 2011/4296/I

Study design

Parallel intervention study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

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

Community-based intervention in two Catalan cities. Two other cities serve as the control cities. The intervention cities receive health promotion materials and actions, permanent training of the local coordinators and the development of an assessment and communication plan. This is not the case in the two cities serving as control. Primary and secondary outcomes will be measured in both groups. The intervention lasts 2 years.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Weight
2. Height
3. Waist circumference

All primary outcomes will be measured at the beginning and the end of the study.

Secondary outcome measures

1. Dietary habits
2. Physical activity
3. Sleep quality
4. Quality of life

Will all be measured at the beginning and end of the study

5. Food intake - will be measured at the beginning, the midpoint, and the end of the study

All secondary outcomes to be measured with validated questionnaires

Overall study start date

01/01/2012

Completion date

31/12/2014

Eligibility

Key inclusion criteria

Healthy children aged 8 to 10 years

Participant type(s)

Patient

Age group

Child

Lower age limit

8 Years

Upper age limit

10 Years

Sex

Both

Target number of participants

2140

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/01/2012

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

Spain

Study participating centre

IMIM-Hospital del Mar Medical Research Institute
Barcelona
Spain
08003

Sponsor information

Organisation

Institute of Health Carlos III (Instituto de Salud Carlos III) (Spain)

Sponsor details

C/ Sinesio Delgado, 4
Madrid
Spain
28029

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registro.general@isciii.es

Sponsor type

Research organisation

Website

<http://www.eng.isciii.es/>

ROR

<https://ror.org/00ca2c886>

Funder(s)

Funder type

Research organisation

Funder Name

Instituto de Salud Carlos III

Alternative Name(s)

SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III
Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location
Spain

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	29/08/2014		Yes	No
Other publications		01/11/2018	27/09/2019	Yes	No
Other publications		03/10/2024	07/10/2024	Yes	No