

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

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<b>Registration date</b> 01/08/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/10/2024	<b>Condition category</b> 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?
<a href="#">Protocol article</a>	protocol	29/08/2014		Yes	No
<a href="#">Other publications</a>		01/11/2018	27/09/2019	Yes	No
<a href="#">Other publications</a>		03/10/2024	07/10/2024	Yes	No