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

Submission date	Recruitment status No longer recruiting	Prospectively registeredProtocol		
22/07/2014				
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
01/08/2014		Results		
Last Edited		Individual participant data		
07/10/2024	Nutritional, Metabolic, Endocrine	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 (Institute de Salud Carlos III), Feder, Madrid (Spain).

Who is the main contact? Dr Helmut Schröder hschroeder@imim.es

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

- 1. Weight
- 2. Height
- 3. Waist circumference

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

Key secondary outcome(s))

- 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

Completion date

31/12/2014

Eligibility

Key inclusion criteria

Healthy children aged 8 to 10 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

10 years

Sex

All

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)

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, La misión del Instituto de Salud Carlos III (ISCIII), ISCIII

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Spain

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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	, ,		No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes