

OBESCAT Study 2006: randomised clinical trial to assess the efficacy of an intervention in order to reduce the body mass index in adolescents in Catalonia

Submission date 11/10/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/11/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2021	Condition category 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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

OBESCAT Study 2006: randomised clinical trial to assess the efficacy of an intervention in order to reduce the body mass index in adolescents in Catalonia

Acronym

OBESCAT

Study objectives

A regular systematic educational intervention by primary care paediatricians will reduce the Body Mass Index (BMI) of the overweight and obese adolescents.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Ethics Committee of Clinical Investigation at the Institute of Health Care, Santa Caterina Hospital (Comite etic d'investigacio clinica de l'institut d'assistencia sanitaria del Hospital Santa Caterina) on the 2nd March 2006.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Overweight and obesity

Interventions

Intervention:

Diet and exercise education and counselling. Weight, height, BMI, waist and hip perimeter and blood pressure measures will be taken at each visit. A questionnaire about eating and physical

activity habits and the AF-5 autoconcept questionnaire will be filled by the adolescent at the inclusion and final visits. The number of scheduled visits will be 6 (at inclusion, month 1, 3, 6, 9 and 12).

Control:

Adolescents in the control group will follow usual care given by paediatricians. Weight, height, BMI, waist and hip perimeter and blood pressure measures will be taken at each visit. A questionnaire about eating and physical activity habits and the AF-5 autoconcept questionnaire will be filled by the adolescent at the inclusion and final visits. The number of scheduled visits will be 2 (inclusion visit and final visit at 12 months).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Reduction in BMI.

Secondary outcome measures

1. Social-economic class
2. Eating and physical activity habits
3. Emotional status (AF-5)

Overall study start date

01/06/2006

Completion date

01/06/2008

Eligibility

Key inclusion criteria

1. Adolescents aged 10 to 14 years
2. Overweight (BMI greater than 85th percentile) or obese (BMI greater than 95th percentile)

Participant type(s)

Patient

Age group

Child

Lower age limit

10 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

200

Total final enrolment

174

Key exclusion criteria

1. Adolescents following an intervention to reduce BMI at the moment of inclusion
2. Morbid obesity
3. Secondary obesity
4. Bulimia nervosa
5. Adolescents with poor mental function, or any other reason to expect that the patient may have difficulty in complying with the requirements of the study
6. Adolescents participating in another clinical trial in the last four weeks

Date of first enrolment

01/06/2006

Date of final enrolment

01/06/2008

Locations

Countries of recruitment

Spain

Study participating centre

Plaza de la Vila 15

Barcelona

Spain

08921

Sponsor information

Organisation

Sant Ramon SL Medical Centre and the Sardenya Primary Care Centre (Spain)

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Research organisation

Funder Name

The Spanish Paediatric Association (Asociación Española de Pediatría [AEP]) (Spain) - awarded Nutriben prize

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		06/07/2012	10/06/2021	Yes	No