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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

Registration date
06/11/2007

Overall study status
Completed

Last Edited
10/06/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Overweight and obesity

Interventions
Intervention:
Diet and exercice 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(s)
Reduction in BMI.

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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
14 years

Sex
All

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)

Funder(s)

Funder type
Research organisation

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

Results and Publications

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