Efficacy of an educational school-based intervention to reduce prevalence of obesity in childhood in Catalonia

Submission date Recruitment status Prospectively registered 24/05/2010 No longer recruiting [X] Protocol [] Statistical analysis plan Registration date Overall study status 28/05/2010 Completed [X] Results [] Individual participant data Last Edited Condition category 24/05/2018 Nutritional, Metabolic, Endocrine

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

C/Sant Llorenç, nº 21 Reus Spain 43201

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Randomised controlled clinical trial to assess the efficacy of an educational school-based intervention to reduce prevalence of obesity in childhood in Catalonia

Acronym

EdAl

Study objectives

A regular systematic educational intervention in primary school improves lifestyle and reduces obesity.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Comite etic d'investigacio clinica de l'Hospital Universitari Sant Joan de Reus approved on the 29th July 2008 (ref: 08-07-24/07aclproj1)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

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

Intervention:

Four educational activities/year for 3 years (a total of 12 activities), of 8 nutritional objectives and physical activity performed by health agents in primary schools. Weight, height, body mass index (BMI) and waist circumference measures will be taken at each year by 3 years. A questionnaire about eating and physical activity habits questionnaire will be filled by the parents each year, 3 times.

Control:

Scholars will follow usual activities in primary schools. Weight, height, BMI and waist circumference measures will be taken at each year by 3 years. A questionnaire about eating and physical activity habits questionnaire will be filled by the parents at the inclusion and final visits.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

To reduce prevalence of obesity.

All measures have taken in May of 2006, 2007, 2008, 2009, 2010.

Secondary outcome measures

- 1. To improve dietary and physical activity habits
- 2. To measure weight, height, BMI, waist circumference measures will be taken at each visit

All measures have taken in May of 2006, 2007, 2008, 2009, 2010.

Overall study start date

01/04/2006

Completion date

30/12/2010

Eligibility

Key inclusion criteria

- 1. Primary scholars aged 6 to 9 years from Cambrils, Reus, Salou and Vilaseca
- 2. Public and private schools

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

9 Years

Sex

Both

Target number of participants

700 participants in control and 700 participants in intervention groups

Key exclusion criteria

Not adequate age

Date of first enrolment

01/04/2006

Date of final enrolment

30/12/2010

Locations

Countries of recruitment

Spain

Study participating centre

C/Sant Llorenç, nº 21

Reus Spain

43201

Sponsor information

Organisation

University of Rovira i Virgili (Universitat Rovira i Virgili) (Spain)

Sponsor details

Facultat de Medicina i Ciències de la Salut C/Sant LLorenç, nº 21 Reus Spain

43201

Sponsor type

University/education

Website

http://www.urv.cat

ROR

https://ror.org/00g5sqv46

Funder(s)

Funder type

Government

Funder Name

Reddis Private Foundation (Fundació Privada Reddis) (Spain)

Funder Name

Municipality of Reus (Ajuntament de Reus) (Spain)

Funder Name

Ministry of Health (Conselleria de Salut) (Spain)

Funder Name

Government of Catalonia (Generalitat de Catalunya) (Spain)

Alternative Name(s)

Government of Catalonia

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Spain

Funder Name

Central Markey of Reus (Mercat Central de Reus) (Spain)

Funder Name

Protected Designation of Origin Siurana (DOP Siurana) (Spain)

Funder Name

La Morella Nuts (Spain)

Funder Name

Technological Centre of Nutritional Health CT09-1-0019 (Centre Tecnològic de Nutrició i Salut) (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	27/02/2011		Yes	No
Results article	results	14/02/2014		Yes	No
Results article	4-year follow-up results	05/01/2018		Yes	No