# Exercise looks after you: Piloting a programme to prevent obesity in children

Submission date	Recruitment status	Prospectively registered		
28/11/2007	No longer recruiting	Protocol		
Registration date	Overall study status	Statistical analysis plan		
02/01/2008	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
31/12/2020	Nutritional, Metabolic, Endocrine			

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Narcis Gusi

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

**Secondary identifying numbers** 98//2007

# Study information

#### Scientific Title

Exercise looks after you: Piloting a programme to prevent obesity in children

#### **Acronym**

ETCO198/07

#### **Study objectives**

1. The addition to usual care of an exercise referral from paedriatic team to a supervised exercise programme is effective and cost-effective compared to usual care

2. In addition to the exercise included in the programme, the programme is effective in increasing the level of physical activity in children

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Approved by the Bioethical Committee of the University of Extremadura on 31 October 2007 (ref: 98/2007)

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

#### Study type(s)

Not Specified

#### 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 group: The 6-month programme includes two one-hour sessions of an exercise programme per week. Each session includes 20-minute physical exercise to improve fitness, a 30-minute activity to improve sport skills, and 10-minute of healthy lifestyle advice (nutrition, possibilities of doing physical exercise during leisure time).

Control group: Usual care only

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

- 1. Level of physical activity (minutes per week) in sports and leisure time, assessed by a questionnaire at 12 months
- 2. Fitness tests (agility, hand-grip, jump test, velocity, endurance, flexibility, body composition, waist-hip index) at baseline and 3 months
- 3. Health care costs, assessed at baseline and 3 months
- 4. Health-related quality of life, measured using the EuroQol EQ-5D, EQ-5D (Child) and PedsQSl questionnaires at 12 months

#### Secondary outcome measures

- 1. Nutritional intake (24 h recall), assessed at baseline and 3 months
- 2. Blood samples (cholesterol, glucose, Hb1Ac), assessed at baseline and 3 months

#### Overall study start date

30/11/2007

#### Completion date

15/06/2008

# **Eligibility**

#### Key inclusion criteria

- 1. Children aged 8 to 12 years old
- 2. Obesity type I and II (Body Mass Index >= age and gender adjusted 95 percentile)
- 3. Capacity to walk for 10 minutes

#### Participant type(s)

**Patient** 

#### Age group

Child

#### Lower age limit

8 Years

#### Upper age limit

12 Years

#### Sex

Both

#### Target number of participants

200

#### Total final enrolment

151

#### Key exclusion criteria

- 1. Diabetes type I
- 2. Hyperactivity
- 3. Morbid obesity
- 4. Contraindications to do exercise (biological or mental)

#### Date of first enrolment

30/11/2007

#### Date of final enrolment

15/06/2008

# Locations

#### Countries of recruitment

Spain

# Study participating centre Faculty of Sports Sciences

Caceres Spain 10071

# Sponsor information

#### Organisation

University of Extremadura (Spain)

#### Sponsor details

Avda Elvas s/n Badajoz Spain 06071 +34 92 428 93 05 vicein@unex.es

#### Sponsor type

University/education

#### Website

http://www.unex.es

#### **ROR**

https://ror.org/0174shg90

# Funder(s)

#### Funder type

Government

#### **Funder Name**

University of Extremadura (Spain)

#### **Funder Name**

Health & Dependence Department and Young & Sports Department of Junta de Extremadura. (ref. 118/06) (Spain)

#### **Funder Name**

Innovation and Research Department of Junta de Extremadura (ref: GRU07106) (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?
Results article	results	01/09/2018	31/12/2020	Yes	No