

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

Submission date

28/11/2007

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

02/01/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

31/12/2020

Condition category

Nutritional, Metabolic, Endocrine

☐ 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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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

ETCOI98/07

Study objectives

1. The addition to usual care of an exercise referral from paediatric 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 \geq 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

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Sponsor information**Organisation**

University of Extremadura (Spain)

Sponsor details

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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