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A physical activity and family-based intervention in pediatric obesity prevention in the school setting

Submission date
23/10/2014

Recruitment status
No longer recruiting

Registration date
07/11/2014

Overall study status
Completed

Last Edited
07/11/2014

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Obesity is a major public health concern. There are worrying trends in Europe, with evidence suggesting that levels are rising and that the rise is consistent across most European countries. In Portugal there is evidence for accelerating rates of overweight and obesity in children. Obesity is related to several heart-related disease risk factors and metabolic problems, even in childhood, and it is therefore likely to be a major contributor to other diseases and death from heart disease in later years. Less quantifiable - but equally important - costs can be attributed to psychological stress, social problems and bullying. The cause of obesity is likely to be rooted in the genetic make-up, critical environmental influences, and energy balance behaviours: physical activity (PA) and diet. A range of additional psychosocial and demographic influences can modify these relationships. We have very limited information that address these subtle and complex relationships. Schools are a good place for implementation of interventions, as they have continuous, intensive contact with children during their formative years. School infrastructure and physical environment, policies, curricula, and personnel have great potential to positively influence child health. Despite the apparent advantages of addressing obesity in schools, evidence of effectiveness has led some to question the wisdom of allocating scarce resources to school-based programs. The main aim of this study is to develop, implement and evaluate a culturally appropriate school-based intervention that promotes healthy eating behaviours and increased PA to prevent obesity.

Who can participate?
Boys and girls who can engage in physical activity enrolled in the 5, 6, and 7th grades, attending the participating schools.

What does the study involve?
Participants were randomly allocated to one of three groups. The first (control) group will be given general information regarding eating and PA behaviours; the second group, besides the standard counselling, will be provided with two additional hours of formal PA and an educational program; the third group, in addition to the standard counselling and the two additional hours of formal PA, will be provided with a parents health and weight educational program,

implementing principles and basic knowledge within the components of PA, eating behaviour and well-being designed to influence the healthy choices of the entire family. We will assess sedentary behaviour, physical activity, cardiorespiratory fitness and body composition. We also will look at three sets of perceived personal, social, and physical and social environmental factors that hold great promise for understanding and predicting PA behaviour.

What are the possible benefits and risks of participating?
Participants have 30 classroom sessions addressing healthy lifestyles through increased PA and healthy diet. Participants are provided with all assessments and related counselling information based upon the results. Considering that all assessments are performed by trained personal, no risks are associated.

Where is the study run from?
The study is run in the public schools of the Oeiras Municipality, with some of the assessment made in the Exercise and Health Laboratory, Faculty of Human Kinetics, University of Lisbon, Portugal.

When is the study starting and how long is it expected to run for?
September 2010 to September 2013.

Who is funding the study?
Portuguese Foundation for Science and Technology (Portugal).
Who is the main contact?
Prof Luis Sardinha
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Contact information

Type(s)
Scientific

Contact name
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Estrada da Costa
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Additional identifiers

Protocol serial number
PTDC/DES/108372/2008

Study information

Scientific Title
A Physical activity and family-based intervention in pediatric obesity prevention in the school setting: a randomised controlled trial

Acronym
PESSOA

Study objectives
1. Standard counseling and two additional hours of formal physical activity, together with a parents health and weight educational program, will induce significant impact on sedentary behavior, physical activity and body composition, as compared with a control group with standard protocol with general information regarding eating and physical activity behaviors.
2. Standard counseling and two additional hours of formal physical activity, together with a parents health and weight educational program, will induce significant impact on sedentary behavior, physical activity and body composition, as compared with a standard counseling providing two additional hours of formal physical activity and an educational program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific committee of the Faculty of Human Kinetics of the University of Lisbon

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Physical activity, cardiorespiratory fitness and body composition

Interventions
The study used a group-randomized design in which schools were the unit of randomization and students were the unit of analysis. Schools were randomly allocated to one of two different groups:
1. The first (control) group was intervened with a standard protocol with general information regarding eating and PA behaviors
2. The second group (intervention), besides the standard counseling, was provided a 90-min additional weekly sessions with health and weight educational program and PA activities.
Besides regular physical education classes based on the Portuguese national curriculum (usually one weekly session of 90 min and another of 45 min), students in the intervention group also received a standardized set of extra opportunities for further PA. On these educational sessions, basic knowledge about PA, eating behavior and well-being were taught using an experiential learning methodology in an autonomy supportive style, where the importance of the behavior is valued and can be experienced in consonance with other important life values and goals and, at the same time, be interesting and enjoyable. The classroom lessons deal with healthy nutrition, active living, and healthy lifestyle choices and are provided by the regular classroom teacher, who receives an extensive manual on the lessons. The central theme of the lessons is to enjoy a fit and healthy lifestyle.
Specific topics start with a homework assignment to be completed with the help of parents.

Assessment and awareness of the childs behavior are the central themes of the home assignment. Each classroom lesson consists of theoretical and practical parts, during which knowledge is transferred and subsequently applied through activities like games, puzzles and tests. Each lesson finishes with goal setting by drawing up a joint agreement regarding lifestyle for the period until the next lesson. Educational material and classroom posters for writing down the agreements are part of the provided material.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Sedentary behavior measured objectively with accelerometers and a validated Portuguese version of the Physical Activity Questionnaire (PAQ)
2. Physical activity measured objectively with accelerometers and a validated Portuguese version of the Physical Activity Questionnaire (PAQ)
3. Cardiorespiratory fitness is assessed by the 20-meter multi-stage shuttle run test and by a multi-stage maximal bicycle ergometer test
4. Body composition is assessed by dual-energy X-ray absorptiometry (DXA) and by standard anthropometric procedures

All primary outcomes are assessed at baseline and at the end of the intervention.

Key secondary outcome(s)
1. Academic achievement
2. Health-related quality of life
3. Perceived personal, social, and physical and social environmental factors

The following questionnaires were also used: the validated Portuguese version of the Kidscreen-10, to measure QoL; the validated Portuguese version of the BREQ-2, for the Behavioral Regulations for Exercise; and, a selection of the parental support, parental encouragement, peer support and teacher support-related items present in the questionnaire used in the Personal and Environmental Associations with Childrens Health (PEACH) study, to assess perceived social support. Academic performance is assessed using the marks students had, at the end of their academic year, in mathematics, language (Portuguese), foreign language (English), and sciences. All secondary outcomes are assessed at baseline and at the end of the intervention.

Completion date
01/09/2013

Eligibility

Key inclusion criteria
Boys and girls without contraindications for physical activity enrolled in the 5, 6, and 7th grades, attending 14 high schools in the Oeiras Municipality.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Limitations for physical activity practice in Physical Education classes.

Date of first enrolment
01/09/2010

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
Portugal

Study participating centre
Estrada da Costa
Cruz-Quebrada Dafundo
Portugal
1499-002

Sponsor information

Organisation
Portuguese Foundation for Science and Technology (Portugal)

ROR
https://ror.org/00snfqn58

Funder(s)

Funder type
Research organisation

Funder Name
Portuguese Foundation for Science and Technology (Portugal)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration