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A 12-week after-school physical activity improves endothelial cell function in overweight and obese children

Submission date
15/02/2012

Recruitment status
No longer recruiting

Registration date
24/02/2012

Overall study status
Completed

Last Edited
12/10/2016

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The arteries of obese children could be just as clogged as those of middle-aged people. This build-up (atherosclerosis) could put children at risk for strokes or heart disease as early as age 30. Therefore, lifestyle changes and preventative measures are necessary to reduce and prevent childhood obesity. Endothelial progenitor cells (EPCs) are a type of cell involved in the regeneration of the lining of blood vessels. Regular physical exercise has been shown to mobilise EPCs from the bone marrow, which then participate in the repair of blood vessels and the formation of new vessels. The aim of this study is to investigate the effects of an after-school aerobic and resistance exercise programme on EPCs in overweight and obese children.

Who can participate?
Overweight and obese children aged 12-13

What does the study involve?
Participants are randomly allocated to either the exercise group or the control group. Participants in the control group are advised to maintain their usual activities of daily living during the study. The exercise group participate in a 12-week exercise programme consisting of combined aerobic and resistance exercise on 3 days per week (i.e., Monday, Wednesday and Friday). Each 80-minute exercise programme includes 10 minutes of warm-up activities and 10 minutes of cool-down activities after school. All training sessions are supervised by two experienced trainers. At the start and the end of the study both groups provide blood samples which are used to measure the levels of blood cells including EPCs. Both groups also undergo the carotid intima-media thickness test, which measures the thickness of the inner two layers of the carotid artery, a marker of heart disease and early atherosclerosis.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. Dong-A University and Cell Therapy Research Center (South Korea)
2. Research Institute of Bioscience and Biotechnology (South Korea)

When is the study starting and how long is it expected to run for?
March to July 2010

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mr Jong-Hwan Park

Contact information

Type(s)
Scientific

Contact name
Mr Jong-Hwan Park

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A 12-week after-school physical activity improves endothelial cell function in overweight and obese children: a randomised controlled study

Study objectives
A regular exercise programme for overweight children would elevate and improve the function of circulating endothelial progenitor cells.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Dona-A university ethics committee - Busan, Rep. of Korea, 04/03/2010, ref : 2010/25

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Obesity

Interventions
Children randomised to the exercise group or the control group.

The 12-week exercise programme intervention consisted of 3 days of combined aerobic and resistance exercise per week (i.e., Monday, Wednesday and Friday).

Each 80-minute exercise programme included 10 minutes of warm-up activities and 10 minutes of cool-down activities after school. All training sessions were supervised by two experienced trainers.

1. Aerobic exercise consisted of 30 minutes of treadmill walking and/or running at 50-70% of the heart rate reserve (HRR). Participants performed the exercise programme for 30 minutes at 50-60% of the HRR during weeks 1 through 6. After week 6, the emphasis was placed on reaching and maintaining an exercise intensity of approximately 60-70% of the HRR for 30 minutes.
2. Resistance exercise consisted of two rotations of a circuit of seven exercises with less than 30 seconds of rest between exercises. Participants trained on the same equipment used for the 60% of one repetition maximum at 8-12 repetition assessments. Each section included the following dynamic exercises: bench presses, biceps curls, triceps extensions, leg presses, leg extensions, leg curls and calf raises.

Intervention Type
Behavioural

Primary outcome measure

Percentage of CD34+, CD133+ and endothelial progenitor cells (EPCs) (CD34+/CD133+) at baseline and 12 weeks

Secondary outcome measures
1. Body mass index and cardiorespiratory fitness at baseline and 12 weeks
2. Concentrations of lipid parameters and inflammatory markers at baseline and 12 weeks
3. Carotid intima-media thickness at baseline and 12 weeks

Overall study start date
04/01/2010

Completion date
07/01/2010

Eligibility

Key inclusion criteria
1. Overweight and obese were defined as having a body mass index ≥ the 85th percentile for age and gender, according to the WHO mass index cut-off point
2. Aged 12-13 years, boys and girls
3. Written consent from parents

Participant type(s)
Other

Age group
Child

Lower age limit
12 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
Control (n = 14) or exercise (n = 15) groups

Key exclusion criteria
1. Taking any medication
2. Participants with any disease

Date of first enrolment
04/01/2010

Date of final enrolment
07/01/2010

Locations

Countries of recruitment
Japan

Korea, South

Study participating centre
2-579-15, Mikajima
Saitama
Japan
359-1192

Sponsor information

Organisation
Waseda University

Sponsor details
Tokorozawa
2-579-15, Mikajima
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Sponsor type
University/education

ROR
https://ror.org/00ntfnx83

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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	31/07/2012		Yes	No