

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

<b>Submission date</b> 15/02/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 24/02/2012	<b>Overall study status</b> Completed	
<b>Last Edited</b> 12/10/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## 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

**Contact details**

2-579-15, Mikajima

Tokorozawa

Saitama

Japan

359-1192

## 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  $\geq$  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

Saitama

Japan

359-1192

## 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?
<a href="#">Results article</a>	results	31/07/2012		Yes	No