

# Community-based heart and weight management trial ('Heart and Weightless')

<b>Submission date</b> 13/01/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/02/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/07/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of the study is to find out about the different effects of three exercise modes (aerobic, resistance and combined exercises) on heart disease risk factors in a weight management intervention for women with abdominal obesity.

### Who can participate?

Healthy women aged between 18 and 65 years and waist circumference ( $\geq 85$  cm)

### What does the study involve?

Eligible participants were invited to an orientation where they were provided a detailed study overview, asked for consent, and screened for additional inclusion criteria. Participants were randomly allocated to one of three different exercise groups: aerobic training only, resistance training only, and a combination of aerobic and resistance training.

### What are the possible benefits and risks of participating?

Benefits to those taking part include weight loss and improvements in heart disease risk factors. Possible diverse side effects from exercise test for measuring cardiorespiratory fitness and exercise training. The exercise was planned to be supervised by trained researchers and exercise trainers. No risks were expected over the entire study period.

### Where is the study run from?

The study has been set up by the Korea University in collaboration with University of Seoul.

### When is the study starting and how long is it expected to run for?

The study started in September 2010 and ran until August 2013. Participants were enrolled on the study for a period of almost one year.

### Who is funding the study?

National Research Foundation of Korea (NRF) (South Korea).

### Who is the main contact?

Professor Jina Choo

# Contact information

## Type(s)

Scientific

## Contact name

Prof Jina Choo

## Contact details

Anam-Dong  
Seongbuk-Gu  
Seoul  
Korea, South  
136-705

# Additional identifiers

## Protocol serial number

NRF 2010-0022022

# Study information

## Scientific Title

Community-based heart and weight management trial

## Acronym

HEART-WEIGHT

## Study objectives

Primary hypothesis: in a weight management intervention different exercise modes (aerobic, resistance and combined exercises) would have significant differential effects on markers of subclinical atherosclerosis, cardiometabolic risk factors, and psychosocial/behavioral factors among women with abdominal obesity.

Secondary hypotheses: to determine associations between psychosocial/behavioral factors, associations between psychosocial/behavioral factors and cardiometabolic factors, and associations between abdominal obesity and cardiometabolic/subclinical atherosclerosis markers using both baseline and longitudinal data.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Institutional Review Board at Korea University, 01/04/2011, KU-IRB-11-10-A-2

## Study design

Randomized controlled trial

## Primary study design

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Cardiovascular health

## **Interventions**

We conducted two consecutive types of intervention (diet alone vs diet plus exercise intervention) in a sequence over 12 months in a weight management program. The 12-month study period had a diet-alone intervention for the first 3 months and a diet-plus-exercise intervention for the next 9 months according to exercise modes; the diet-alone intervention was implemented by requesting all three groups not to do exercise for the first 3 months.

The study was a randomized intervention with three different exercise groups:

1. Aerobic training only
2. Resistance training only
3. A combination of aerobic and resistance training

The intervention assignment was implemented with a different ratio (n=50 for aerobic exercise, n=30 for resistance exercise, and n=30 for combination exercise) by means of a random allocation computer program. Initially, the aerobic exercise group (n=50) was randomly allocated into two groups, one group with (n=30) and the other group without a behavioral therapy (n=20). Since there were no significant differences in any study variables between the aerobic exercise groups with and without behavioral therapy, we pooled the participants of the two groups into one aerobic exercise group (n=50) for the present study. This study was a single-blinded trial; assessors for all outcomes were blinded to participant group assignment, and all outcome data were kept blinded until the final data entry for the 12-month assessment was completed.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Endothelial dysfunction, as measured by flow-mediated dilation (FMD), at baseline, 3, 6 and 9 months

## **Key secondary outcome(s)**

1. Aortic stiffness, as measured by carotid-femoral pulse wave velocity
2. Carotid atherosclerosis, as measured by carotid intima-media thickness
3. Cardiometabolic factors
4. Psychosocial factors
5. Quality of life

Measured at baseline, 3, 6 and 9 months

## **Completion date**

31/08/2013

## Eligibility

### Key inclusion criteria

1. Healthy women aged between 18 and 65 years
2. Elevated waist circumference (greater than or equal to 85 cm) according to the criteria for abdominal obesity as defined by the Korean Society for the Study of Obesity (Lee et al. 2007)
3. Willing to be randomly assigned to one of three different exercise modes (i.e., aerobic, resistance and combination exercise training)

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Lower age limit

18 years

### Sex

Female

### Key exclusion criteria

1. Current medical conditions such as cardiovascular diseases, diabetes or cancers requiring physician supervision
2. Physical limitations restricting exercise ability
3. Use of hormone therapy
4. Participation in weight loss intervention during the last year
5. Weight change in the 4 weeks prior to participation in our study.

### Date of first enrolment

01/09/2010

### Date of final enrolment

31/08/2013

## Locations

### Countries of recruitment

Korea, South

### Study participating centre

Anam-Dong

Seoul

Korea, South  
136-705

## Sponsor information

### Organisation

National Research Foundation of Korea (NRF) (South Korea)

### ROR

<https://ror.org/013aysd81>

## Funder(s)

### Funder type

Government

### Funder Name

National Research Foundation of Korea (NRF) (Korea, South), No. 2010-0022022

## Results and Publications

### 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	10/07/2014		Yes	No