

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

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

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Korea, South
136-705

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

110

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)

Sponsor details

25 Heonreung-ro

Seocho-gu

Seoul

Korea, South

137-748

Sponsor type

Government

Website

http://www.nrf.re.kr/nrf_eng_cms/

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

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	10/07/2014		Yes	No