

# Influences of short-term normobaric hypoxic training on metabolic syndrome-related markers

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|----------------------------------------|----------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>18/08/2017   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                                | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>25/08/2017 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                                | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>24/08/2017       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Individual participant data |
|                                        |                                                                | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Hypoxic training involves training while breathing hypoxic (low oxygen) air. Although not commonly used, hypoxic training may be beneficial for people with clinical conditions such as coronary artery (heart) disease and chronic obstructive pulmonary (lung) disease. However, the effects of hypoxic training vary greatly according to the oxygen level, exercise intensity, time and duration, and also vary considerably among individuals. The aim of this study is to examine the effects of hypoxic training on factors related to metabolic syndrome (a combination of diabetes, high blood pressure and obesity).

### Who can participate?

Men aged 18 or over

### What does the study involve?

Participants are divided into two groups based on their body mass index. Participants in the overweight and normal-weight groups are then randomly allocated into either the hypoxic exercise group (hypoxic overweight and hypoxic normal-weight) or the normoxic exercise group (normoxic overweight and normoxic normal-weight). Participants perform treadmill exercise three days per week for four weeks under either hypoxic (low oxygen) or normoxic (normal oxygen) conditions, for 50 minutes (including 5 minutes warm-up and cool-down periods) after a 30-minute rest period. Markers of metabolic syndrome are measured using blood sampling at the start and the end of the study.

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

These results may show that hypoxic training could be useful for improving arterial (blood vessel) stiffness, circulatory system function, body composition and metabolism in adult men.

### Where is the study run from?

Gifu University (Japan)

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

March 2014 to May 2015

Who is funding the study?  
University of Ulsan (South Korea)

Who is the main contact?  
Dr Sohee Shin

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Sohee Shin

**Contact details**  
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## Additional identifiers

**Protocol serial number**  
-

## Study information

**Scientific Title**  
Influences of short-term normobaric hypoxic training on metabolic syndrome-related markers in overweight and normal-weight men: a randomised controlled trial

**Study objectives**  
Short-term normobaric hypoxic training influences metabolic syndrome-related markers in overweight and normal-weight men positively.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Institutional review board of the Gifu University School of Medicine, 06/03/2013, ref: 24-392

**Primary study design**  
Interventional

**Study design**  
Interventional randomised controlled trial

**Study type(s)**

Treatment

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

Metabolic syndrome

**Interventions**

Forty-one Japanese men were included and were divided into two groups based on their body mass indexes (BMIs): BMI  $\geq 25$  or BMI  $< 25$ . Participants in the overweight and normal-weight groups were randomised into the hypoxic exercise group (hypoxic overweight, HO; hypoxic normal-weight, HN) or the normoxic exercise group (normoxic overweight, NO; normoxic normal-weight, NN). Subjects performed treadmill exercise three days per week for four weeks at an exercise intensity of 60% maximum heart rate (HR), under either normobaric hypoxic or normobaric normoxic conditions, for 50 min (including 5 min warm-up and cool-down periods) after a 30-min rest period. Duration of follow-up: 4 weeks.

**Intervention Type**

Other

**Primary outcome(s)**

Metabolic syndrome-related markers, measured using blood sampling at baseline and 1 month

**Key secondary outcome(s)**

Body composition, measured using body composition analyzer (TANITA Co., Tokyo, Japan) at baseline and 1 month

**Completion date**

30/05/2015

**Eligibility****Key inclusion criteria**

1. All patients admitted to one of the participating wards
2. Aged 18 years or over
3. Able to provide informed consent to participate

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Key exclusion criteria**

1. Coronary heart disease
2. Cardiac insufficiency
3. Pulmonary disease
4. Uncontrolled hypertension

**Date of first enrolment**

30/03/2014

**Date of final enrolment**

30/08/2014

**Locations****Countries of recruitment**

Japan

**Study participating centre**

Gifu University

501-1194

**Sponsor information****Organisation**

University of Ulsan

**ROR**

<https://ror.org/02c2f8975>

**Funder(s)****Funder type**

University/education

**Funder Name**

University of Ulsan

**Alternative Name(s)**

UOU

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Korea, South

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sohee Shin.

**IPD sharing plan summary**

Available on request