

# The effect of exercise on fasting insulin and fitness levels in people with spinal cord injury: Development of evidence-based exercise programs

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 31/05/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/05/2017	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Individuals with spinal cord injury generally have a sedentary (inactive) lifestyle, which negatively impacts their fitness level and quality of life. Moreover, those with SCI are at increased risk of developing long-term health conditions such as type 2 diabetes, heart disease and metabolic syndrome (a group of conditions which increase a person's risk of heart attack or stroke). Therefore, promoting an active lifestyle for those with SCI is important for the prevention of these diseases. The aim of this study are to assess the effects of personalized exercise programs on insulin (the hormone which converts sugar in the blood into stored sugars) and fitness levels of people with spinal cord injury.

### Who can participate?

Patients with Spinal cord injury

### What does the study involve?

Patients are randomly allocated to either the exercise group or the control group. Those in the exercise group receive a six-week combined exercise program. Participants will exercise for 60 minutes per session, three times per week for six weeks. The daily exercise programs consist of a 25-minute warm up consisting of 5 min of joint exercises, 15 min of exercise on an arm ergometer, and 5 min of stretching, followed by a 30-minute exercise program (resistance, circuit, and aerobic training), and a 5-minute cool down (stretching). Those in the control group are instructed to continue with their usual daily activities. At the start of the study and after six weeks, participants in both groups provide blood samples to assess their insulin and blood sugar levels, and complete questionnaires about their quality of life and mood. In addition, participants have their fitness levels assessed.

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

Participants allocated to the exercise group will receive the thera-band, and results of clinical tests. There are no known risks to participants.

Where is the study run from?  
Fitness Center, Yonsei University (South Korea)

When is the study starting and how long is it expected to run for?  
April 2014 to December 2014

Who is funding the study?  
National Rehabilitation Research Institute (South Korea)

Who is the main contact?  
1. Professor Justin Jeon (scientific)  
2. Dr Dong-Il Kim (public)

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## **Secondary identifying numbers**

1040917-201404-HRBR-152-03

# **Study information**

## **Scientific Title**

A randomized controlled trial of six-weeks combined exercise program on fasting insulin and fitness levels in individuals with spinal cord injury

## **Study objectives**

A six-week combined exercise program will improve on fasting insulin and fitness levels in individuals with spinal cord injury.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Institutional Ethics Review Board at Yonsei University College of Medicine, 04/04/2014, ref: 1040917-201404-HRBR-152-03

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Other

## **Study type(s)**

Quality of life

## **Participant information sheet**

No participant information sheet available

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

Spinal cord injury

## **Interventions**

Participants will be randomized to one of two groups using the minimization method.

Intervention group: Participants will receive a 6-week combined exercise program. Participants will exercise for 60 minutes per session, three times per week for six weeks. The daily exercise programs consist of a 25-minute warm up consisting of 5 min of joint exercises, 15 min of exercise on an arm ergometer, and 5 min of stretching, followed by a 30-minute exercise program (resistance, circuit, and aerobic training), and a 5-minute cool down (stretching).

Control group: Participants will be instructed to continue with their usual daily activities.

Participants in both groups will be followed up after six weeks.

## **Intervention Type**

Other

## **Primary outcome measure**

1. Fasting glucose is measured using ADVIA 1650 Chemistry System at baseline and six weeks
2. Insulin is measured using Roche Chemistry System at baseline and six weeks
3. Insulin resistance will be estimated according to the homeostasis model assessment of insulin resistance (HOMA-IR) index at baseline and six weeks

## **Secondary outcome measures**

1. Total cholesterol (TC), triglyceride (TG), high density lipoprotein cholesterol (HDL-C), and low density lipoprotein cholesterol (LDL-C) levels will be measured using an ADVIA 1650 Chemistry System at baseline and six weeks
2. Upper body strength will be measured by a hand-held dynamometer at baseline and six weeks
3. Vo2 peak will be assessed through maximal graded exercise tests, performed using a ramp protocol at baseline and six weeks.
4. Quality of life will be measured using the SF-36 questionnaire at baseline and six weeks
5. Anxiety and depression will be measured using the Generalized Anxiety Disorder 7-item (GAD-7) scale and Patient Health Questionnaire (PHQ-9) at baseline and six weeks

## **Overall study start date**

01/02/2014

## **Completion date**

22/12/2014

# **Eligibility**

## **Key inclusion criteria**

1. An SCI >6 months
2. Age between 18 and 65 years
3. No regular exercise over the prior six months

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

18 individuals with SCI (exercise group: 12, control group: 6)

**Key exclusion criteria**

1. Cardiovascular disease
2. Uncontrolled type 2 diabetes
3. Uncontrolled hypertension
4. Pressure ulcers
5. Orthopedic problems

**Date of first enrolment**

04/04/2014

**Date of final enrolment**

01/09/2014

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

Korea, South

**Study participating centre**

**Yonsei University College of Medicine**

134 Shinchon-Dong

Seodaemun-Gu

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120-749

**Sponsor information****Organisation**

Yonsei University

**Sponsor details**

Department of sport industry studies

134 Shinchon-DongSeodaemun-Gu

Seoul

Korea, South

120-749

**Sponsor type**

University/education

**ROR**

<https://ror.org/01wjejq96>

# **Funder(s)**

## **Funder type**

Research organisation

## **Funder Name**

National Rehabilitation Research Institute

# **Results and Publications**

## **Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal

## **Intention to publish date**

31/12/2017

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

The datasets generated during and/or analysed during the current study are/will be available upon request from [hiop1@hanmail.net](mailto:hiop1@hanmail.net)

## **IPD sharing plan summary**

Not provided at time of registration