

# Guided exercise intervention for improving physical fitness and weight control in overweight and obese males and females

**Submission date**  
29/09/2009

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
09/11/2009

**Overall study status**  
Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**  
09/11/2009

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

☐ Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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401001

## Additional identifiers

### Protocol serial number

EWI-study; K-S shp:n Dnro 4U/2009

## Study information

### Scientific Title

Exercise and weight control intervention for improving physical fitness - fitness line algorithm validation: a randomised controlled trial

## **Acronym**

EWI-study

## **Study objectives**

1. Guided exercise is more effective for improving physical fitness and weight control than unguided exercise. The most sensitive changes will be seen in maximal oxygen uptake (max VO<sub>2</sub>) and gut microbiota after a short-term exercise program while the differences will be more pronounced in heart rate variability (HRV) and body composition after long-term exercise program.
2. There will be high dropout after a short-term intervention. Overweight and obese people need guidance and monitoring of their physical condition to motivate them towards continuing exercise and weight control. To establish "habitual exercise" requires long term guidance and commitment.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics Committee of Central Finland Health Care District, Jyväskylä, Finland, approved on the 17th June 2009 (ref: K-S shp:n Dnro 4U/2009)

## **Study design**

Randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Overweight/obesity

## **Interventions**

Phase I (6-week intervention):

Group 1 - exercise follows guidance from a wrist computer: subjects will follow the daily guidance of the device to exercise (Nordic break walking) 30 minutes to 1 hour each time and gradually increase the intensity and duration. The intensity of exercise will be checked every 2nd week and the guidance will be modified accordingly.

Group 2 - general training advice but no device: subjects will follow the instruction by a researcher to exercise (Nordic break walking) 30 minutes to 1 hour a time and gradually increase the intensity and duration.

Group 3 - weight control follows guidance from a wrist computer: subjects follow the weight guidance from device to change their weight either by eating or exercise. The weight (body composition) will be checked every 2nd week and the guidance will be modified accordingly.

Group 4 - weight control gets general advice but no device: subjects follow the instruction by a nutritionist to change their weight either by eating or exercise.

After the first phase of the study, subjects will not be informed that they will be followed-up for phase II of the study. Thus it can be ensured that the maintenance rate is not interfered with by the participants knowing that they will be followed later.

In study phase II (1-year intervention), all of the subjects will be invited back 6 months after the onset of the phase I study. A wrist computer will be provided to them and subjects will follow the instruction to set the exercise intensity/duration and target weight on the basis of their fitness level and weight to exercise. Those people who are not maintaining their leisure time physical activity (LTPA) will be randomly assigned to two groups. One group will have and one will not have 6 months measurements. Phone call tracking interview will be contacted every 3 months interval to evaluate the maintenance rate.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Efficacy of guided exercise on fitness and weight control: physical fitness and body composition (HRV, gut microbiota, Max VO<sub>2</sub>, fat mass, lean mass) -

1. Daily physical activity and a diet diary will be assessed at baseline, every week during the intervention, at follow-up point 2, and every week during the long term intervention until follow-up point 3
2. Anthropometry and blood pressure will be measured at baseline, half-way through the long-term intervention and at follow-up points 1, 2 and 3. Blood samples will also be taken at this point.
3. Body composition, and the 10-metre walking test will be measured at baseline and every two weeks through the short term intervention until follow-up point 1, and at follow-up point 2, halfway-way through the long term intervention and at follow-up point 3. The treadmill test will also be taken at all of these points apart from follow-up point 3.
4. Faecal samples, basal metabolic rate and max VO<sub>2</sub> will be measured at baseline and follow-up points 1, 2 and 3

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

Maintenance of exercise and weight control intervention:

1. How many people will maintain their physical activity and weight control after a short intervention?
2. What are the reasons for people stopping exercise and weight control after a short intervention?
3. Does long-term guided exercise and weight control intervention help to maintain peoples LTPA and weight control after intervention?

### **Completion date**

31/12/2012

## **Eligibility**

### **Key inclusion criteria**

1. Women and men aged 20 - 50 years
2. Physically inactive (regular exercise less than or equal to two times per week and less than or equal to 45 minutes per session)
3. Body mass index (BMI) greater than 25 kg/m<sup>2</sup> 38 kg/m<sup>2</sup>

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. BMI greater than 38 kg/m<sup>2</sup>
2. Serious cardiovascular or musculoskeletal problems
3. Diagnosed type I diabetes
4. Change in weight more than 5 kg during last 6 months

**Date of first enrolment**

20/06/2009

**Date of final enrolment**

31/12/2012

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

Finland

**Study participating centre**

Department of Health Sciences

Jyväskylä

Finland

401001

**Sponsor information****Organisation**

Suunto Oy (Finland)

**ROR**

<https://ror.org/04n2d2p10>

# Funder(s)

## Funder type

Industry

## Funder Name

Suunto Oy (Finland)

## Funder Name

University of Jyväskylä (Finland) - Wellness Program

# 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="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes