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

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/11/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/11/2009	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 VO2) 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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
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 measure
Efficacy of guided exercise on fitness and weight control: physical fitness and body composition (HRV, gut microbiota, Max VO2, 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 VO2 will be measured at baseline and follow-up points 1, 2 and 3

Secondary outcome measures
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?

Overall study start date
20/06/2009

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^2 38 kg/m^2

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100 women and 100 men

Key exclusion criteria
1. BMI greater than 38 kg/m^2
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
Deparment of Health Sciences
Jyväskylä
Finland
401001

Sponsor information

Organisation
Suunto Oy (Finland)

Sponsor details
c/o Veikko Koivumaa
Valimotie 7
Vantaa
Finland
01510

Sponsor type
Industry

Website
http://www.suunto.com/suunto/main/index.jsp

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

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