

# Effect of physical activity on menopausal symptoms

<b>Submission date</b> 10/12/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 17/12/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/09/2015	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

**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**  
N/A

# Study information

## Scientific Title

Effect of physical activity on menopausal symptoms: a randomised clinical trial

## Study objectives

1. Increasing physical activity alleviates menopausal symptoms.
2. Physical activity increases quality of life of menopausal women through alleviating menopausal symptoms

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Pirkanmaa Hospital District Ethics Committee, 02/12/2008, ref: R07199

## Study design

Randomised controlled clinical trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Quality of life

## 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

Menopausal symptoms

## Interventions

Intervention:

Moderate intensity aerobic training for 6 months, 4 times per week walking (or Nordic walking) for 50 minutes at 60% of maximal oxygen uptake (VO<sub>2</sub>max).

Control:

Continue earlier habits.

Duration of follow-up is 6 months for both arms.

## Intervention Type

Behavioural

**Primary outcome measure**

Vasomotor symptoms as measured with validated scale (Women's Health Questionnaire [WHQ]). WHQ enables assessment of depression, anxiety, sleep problems, somatic symptoms with optional subscales for menstrual problems and sexual difficulties.

Timepoint of the measurements is 0 and 6 months; baseline and end of the trial in both primary and secondary outcomes.

**Secondary outcome measures**

1. Other menopausal symptoms, such as urogenital and cognitive symptoms
2. Physical activity and health-related physical fitness (estimated maximal oxygen consumption, muscle strength)
3. Components of metabolic syndrome (weight, waist circumference, and fasting plasma high density lipoprotein [HDL] cholesterol, triglycerides, glucose and insulin)
4. Workability

Timepoint of the measurements is 0 and 6 months; baseline and end of the trial in both primary and secondary outcomes.

**Overall study start date**

11/01/2009

**Completion date**

31/12/2009

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

1. Symptomatic (severe or very severe or moderate daily hot flushes) women
2. Aged 40 - 60 years
3. No current use of oestrogen hormone treatment (HT, without or with progesterone) or any other treatment or withdrawal (wash-out period 3 months)
4. Sedentary (physical exercise less than twice weekly)
5. Six to 36 months from last menstruation (peri-menopausal)
6. Follicle stimulating hormone (FSH) elevated (at least 30 IU/l)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

100 for the exercise group, 100 for comparison group

**Key exclusion criteria**

1. Physically active women (greater than two times/week, at least 30 minutes)
2. Body mass index (BMI) greater than 35 kg/m<sup>2</sup>
3. Coronary heart disease, orthopaedic or other diseases preventing from exercising

**Date of first enrolment**

11/01/2009

**Date of final enrolment**

31/12/2009

## Locations

**Countries of recruitment**

Finland

**Study participating centre**

UKK Institute for Health Promotion

Tampere

Finland

33501

## Sponsor information

**Organisation**

The Urho Kaleva Kekkonen (UKK) Institute for Health Promotion Research (Finland)

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**Sponsor type**

Research organisation

**Website**

<http://www.ukkinstituutti.fi>

**ROR**

<https://ror.org/05ydecq02>

# Funder(s)

## Funder type

Government

## Funder Name

Academy of Finland (Finland)

## Alternative Name(s)

Suomen Akatemia, Finlands Akademi, Academy of Finland, AKA

## Funding Body Type

Government organisation

## Funding Body Subtype

Universities (academic only)

## Location

Finland

## Funder Name

Ministry of Health and Education (Finland)

## Funder Name

Pirkanmaa Competitive Research Fund (Finland)

## Funder Name

Yrjö Jansson Foundation (Finland)

## Funder Name

Juho Vainio Foundation (Finland)

## Alternative Name(s)

Juho Vainio Foundation, Reppy Institute

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

**Location**

Finland

## 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?
<a href="#">Results article</a>	results	01/08/2012		Yes	No
<a href="#">Results article</a>	results	01/09/2012		Yes	No
<a href="#">Results article</a>	results	11/09/2015		Yes	No