

Effect of physical activity on menopausal symptoms

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

Protocol serial number
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

Study type(s)

Quality of life

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 (VO₂max).

Control:

Continue earlier habits.

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

Intervention Type

Behavioural

Primary outcome(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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/m²
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)

ROR

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

Funder(s)

Funder type

Government

Funder Name

Academy of Finland (Finland)

Alternative Name(s)

Academy of Finland, Suomen Akatemia, Finlands Akademi, AKA

Funding Body Type

Government organisation

Funding Body Subtype

Research institutes and centers

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

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | results | 01/08/2012 | | Yes | No |
| Results article | results | 01/09/2012 | | Yes | No |
| Results article | results | 11/09/2015 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |