ISRCTN54690027 https://doi.org/10.1186/ISRCTN54690027

Effect of physical activity on menopausal symptoms

Submission date	Recruitment status
10/12/2008	No longer recruiting
Registration date	**Overall study status**
17/12/2008	Completed
Last Edited	**Condition category**
14/09/2015	Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 (VO2max).

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^2
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
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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?
Results article	results	01/08/2012		Yes	No
Results article	results	01/09/2012		Yes	No
Results article	results	11/09/2015		Yes	No