

# Exercise and menopausal symptoms: a randomised controlled trial

<b>Submission date</b> 10/11/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/09/2020	<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**  
8367

# Study information

## Scientific Title

The feasibility and acceptability of exercise as a treatment for vasomotor menopausal symptoms: a randomised controlled trial

## Study objectives

Many menopausal women are keen to find alternatives to hormone replacement therapy (HRT); exercise might be a useful intervention in this regard. There has been a lack of robust research on the effects of exercise upon vasomotor symptoms as evidenced by our recent Cochrane review, which concluded that research in this field is very limited and of low quality. Our previous pilot work has already established that exercise is likely to be acceptable to menopausal aged women. In addition, we have now established women's preferences for different types of exercise and modes of delivery. We now need to determine the feasibility and acceptability of the preferred exercise interventions within the context of a randomised controlled trial (RCT). If exercise is shown to be feasible and subsequently effective in a phase III trial, then it would be possible for health professionals to discuss aerobic exercise as an evidence-based treatment option, specifically for the management of vasomotor symptoms.

We will conduct a three-arm RCT with women randomised to one of two exercise interventions or control. The interventions will last 6 months. The primary outcome will be feasibility (adherence and recruitment). Secondary outcomes include quality of life, depression and self-efficacy for exercise.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

West Midlands Local Research Ethics Committee, 04/02/2010, ref: 10/H1208/3a

## Study design

Single-centre randomised interventional treatment trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## 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

Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

### **Interventions**

Physical activity 1: Exercise consultations plus DVD and booklet, plus leaflets

Physical activity 2: Exercise consultations plus support/information groups

Control: Treatment as usual

Duration of treatment: 6 months

Duration of follow-up: 6 months from baseline (i.e. end of treatment)

Study entry: single randomisation only

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Feasibility (recruitment and adherence), measured at baseline and 6-month follow-up

### **Secondary outcome measures**

1. Depression, measured at baseline and 6-month follow-up
2. Menopause-specific quality of life, measured at baseline and 6-month follow-up
3. Physical activity (self report and objective), measured at baseline and 6-month follow-up
4. Self efficacy for exercise, measured at baseline and 6-month follow-up
5. Vasomotor symptoms, measured at baseline and 6-month follow-up

### **Overall study start date**

01/01/2011

### **Completion date**

31/03/2012

## **Eligibility**

### **Key inclusion criteria**

1. Women aged 48 - 57 years who are experiencing vasomotor menopausal symptoms and have not used HRT in the previous 3 months
2. Spontaneously perimenopausal (irregular periods but at least one period in the previous 12 months) or menopausal women (no menstruation for greater than 12 months prior to study)
3. Inactive (not currently involved in a regular programme of exercise three or more times per week for at least 30 minutes per session during the previous 3 months)
4. Not dependent on illicit drugs or alcohol

### **Participant type(s)**

Patient

### **Age group**

Adult

**Sex**

Female

**Target number of participants**

Planned sample size: 165

**Total final enrolment**

261

**Key exclusion criteria**

1. Oral contraceptive, tamoxifen, tibolone and raloxifene usage in previous 3 months
2. Using HRT
3. Unable to provide informed consent
4. Not able to understand English sufficiently to complete the research questionnaires
5. GP considers patient unsuitable for the trial

**Date of first enrolment**

01/01/2011

**Date of final enrolment**

31/03/2012

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

England

United Kingdom

**Study participating centre**

University of Birmingham

Birmingham

United Kingdom

B15 2TT

**Sponsor information****Organisation**

University of Birmingham (UK)

**Sponsor details**

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B15 2TT

**Sponsor type**  
University/education

**Website**  
<http://www.birmingham.ac.uk/index.aspx>

**ROR**  
<https://ror.org/03angcq70>

## Funder(s)

**Funder type**  
Government

**Funder Name**  
National Institute of Health Research (NIHR) (UK) - Research Capacity Development (ref: SRF/08/01/07)

## 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="#">Protocol article</a>	protocol	01/12/2013		Yes	No
<a href="#">Results article</a>	results	01/03/2015		Yes	No
<a href="#">Results article</a>	qualitative results	14/09/2020	16/09/2020	Yes	No