

Exercise and menopausal symptoms: a randomised controlled trial

Submission date 10/11/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 10/11/2010	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 16/09/2020	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

University of Birmingham

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

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

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	01/03/2015		Yes	No
Results article	qualitative results	14/09/2020	16/09/2020	Yes	No
Protocol article	protocol	01/12/2013		Yes	No