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Exercise and menopausal symptoms: a randomised controlled trial

Submission date	Recruitment status	[X] Prospectively registered
10/11/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/11/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/09/2020	Urological and Genital Diseases	

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
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Sponsor information

Organisation
University of Birmingham (UK)

Sponsor details
Department of Primary Care & General Practice
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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?
Protocol article	protocol	01/12/2013		Yes	No
Results article	results	01/03/2015		Yes	No
Results article	qualitative results	14/09/2020	16/09/2020	Yes	No