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Lifestyle in Perimenopause: Exploring a Community Intervention

Submission date 21/10/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 22/10/2024	**Overall study status** Ongoing	
Last Edited 26/08/2026	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

The development of osteoporosis and the associated risk of fractures is a significant concern for women and persons assigned female at birth in later life. Bone density reduces at a faster rate during the perimenopausal years, with those from poorer backgrounds being affected at the highest rate. While bone loss can be slowed through various lifestyle interventions, multiple barriers exist to participating in these activities. This study will explore the experience of perimenopause with lifestyle change and evaluate a multidisciplinary community intervention led by a charity. The intervention includes weekly walks, peer-sharing, and sessions on general health, medications, nutrition, pelvic health, mindfulness, and herbal medicine. The research question is: “Is addressing and raising awareness of the challenges of the perimenopause and menopause experience in a group setting beneficial in helping persons experiencing perimenopause and menopause to take part in activities with the potential to improve bone density and muscle strength?”.

The study aims to explore participants’ experience of menopause symptoms and perceived stress when they're involved in an existing multidisciplinary menopause group-based intervention; provide insights on the acceptability of a group-based intervention providing multidisciplinary health information and peer support; provide potential new insights into the perimenopause and menopause experience; and, inform the development of the intervention and future interventions and scalability of the intervention.

Who can participate?

Persons assigned female sex at birth age 35 years or older, or experiencing premature menopause at any age who are participating in the Health Agency’s “Menopause Walk with a Doc” course starting in early 2025

What does the study involve?

Participants will be invited to complete questionnaires relating to menopause symptoms and perceived stress levels and take part in focus groups or participatory methods. The participatory methods are the creative methods of “Drawing a Timeline” and “Body Mapping”, followed by a recorded discussion connected to the experience. Following the initial analysis of the results, a stakeholder meeting will be held to which participants who have taken part in the intervention

and connected health care and policy workers will be invited. A form of collaborative analysis will be undertaken at this meeting.

What are the possible benefits and risks of participating?
No benefits can be claimed from taking part in the research; however, it is known that such research can be a positive experience for participants. The activities focus on personal experiences, therefore there is a risk that participants may become distressed or upset. If a participant becomes distressed, the activity will be paused and appropriate support sourced for the participant. There is a list of reputable support agencies which will be provided to all participants, the researcher will offer a one-to-one debrief, and further support can be sourced from the polyclinic adjoining the Health Agency, where the research will be taking place.

Where is the study run from?
The study will take place at the Health Agency, Wester Hailes Healthy Living Centre, Edinburgh, UK

When is the study starting and how long is it expected to run for?
September 2021 to December 2026

Who is funding the study?
The Lydia Osteoporosis Project, based at Queen Margaret University, Edinburgh, UK

Who is the main contact?
Becca Freeden, BFreeden@qmu.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

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Integrated Research Application System (IRAS)
349386

Study information

Scientific Title
Exploring Impacts of an Existing Multi-Disciplinary Community Intervention to Support Health and Lifestyle in Menopause and Perimenopause: a mixed-methods study

Study objectives
50% of women will experience an osteoporotic fracture after the age of 50. The development of osteoporosis is multi-factorial, and perimenopause is identified as a key time when there is a risk of bone loss. Some risk factors for osteoporosis are unmodifiable (sex, age, family history and some diseases that affect nutrient absorption) and some are modifiable (adequate quality nutrition, sunlight exposure, weight-bearing exercise with impact, resistance training with heavy weights).

Most women are aware that they need to take part in lifestyle interventions to prevent bone loss, however, there are barriers to taking part in these activities. For example, taking part in a more vigorous exercise programme can be hampered by pain, incontinence or lack of time.

Another risk factor for developing osteoporosis is chronic stress. Being chronically stressed not only makes the likelihood of taking part in physical activity lower, but it also prevents the body from benefitting from some of the positive benefits of exercise when it is done. A review of stress and osteoporosis risk recommended: “… community-building social stress interventions in postmenopausal women … [to] potentially limit bone loss”.

Due to the multiple symptoms of perimenopause and menopause and the many demands of women in midlife, it can be difficult to make positive lifestyle changes to improve future health. Because of the stigma of ageing and the symptoms themselves, the experience can be an isolating one, leading to further mental and physical health problems. Existing literature tells us that community-based interventions that allow for peer-sharing reduce isolation and encourage health-promoting behaviour.

The Health Agency offers one such intervention, with space for movement, sharing and education from a different aspect of wellbeing every week (GP, nutritionist, mindfulness coach, physiotherapist, herbalist and physical activity coordinator). This study will explore the experience of taking part in this intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 16/08/2024, Queen Margaret University Nursing and Paramedic Science Divisional Research Ethics Committee (Queen Margaret University Way, Musselburgh, EH21 6UU, United Kingdom; +44 (0)1314740000; NPSdivrec@qmu.ac.uk), ref: NPSdivrec2024/05

2. Approved 19/12/2024, NHS South East Scotland Research Ethics Committee 2 (NHS Lothian, Waverley Gate, 2 - 4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 (0)7814 764 241; Ruth.Fraser4@nhslothian.scot.nhs.uk), ref: 24-SS-0089

Primary study design
Observational

Study design
A single-centre mixed methods study

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
People who are having difficulty managing symptoms of perimenopause and menopause.

Interventions
Questionnaires (Menopause Rating Scale and Perceived Stress Scale (10-item)) and focus groups will evaluate the intervention and provide information on the feasibility of questionnaires to evaluate future cohorts of the intervention. Questionnaires will take place on weeks 1 and 6 of the intervention and at 6 months follow-up. A focus group will take place within 2 months of the completion of the intervention. Participatory methods and reflective discussion will take place one week before the intervention starts (Drawing a Timeline - a personal history of the participants' journey to the intervention) and one week following the completion of the intervention (Body Mapping - an exploration of how participants view their bodies).

Six months following the intervention, a stakeholder meeting will be held to collaboratively analyse initial findings and explore the scalability of the intervention.

Intervention Type
Behavioural

Primary outcome(s)
The severity of perimenopause/menopause symptoms is measured using the Menopause Rating Scale prior to commencing the intervention, after completion of the intervention, and at 6-month follow-up.

Key secondary outcome(s)
The perceived level of stress is measured using the Perceived Stress Scale (10-item) before commencing the intervention, after completion of the intervention, and at 6-month follow-up.

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Persons assigned female sex at birth
2. Aged 35 years or older, or experiencing premature menopause from any age
3. Enrolled on the Health Agency's "Menopause Walk with a Doc" course
4. Able to speak conversational English (however, if there is an interested participant with a need for an interpreter, if the Health Agency are able to provide this for the course, the research budget for the project will cover the cost of interpretation of the research aspects).

Participant type(s)
Healthy volunteer, Patient, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
35 Years

Upper age limit
100 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Those not meeting the inclusion cliteria will be excluded

Date of first enrolment
09/12/2024

Date of final enrolment
31/10/2026

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
The Health Agency
Wester Hailes Healthy Living Centre, 30 Harvesters Way
Edinburgh
Scotland
EH14 3JF

Sponsor information

Organisation
Queen Margaret University

ROR
https://ror.org/002g3cb31

Funder(s)

Funder type
University/education

Funder Name
Queen Margaret University

Alternative Name(s)
Queen Margaret University, Edinburgh, QMU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available on request from Becca Freeden, BFreeden@qmu.ac.uk. Participants will be given the option to give permission for the sharing of their anonymised data for future ethical research in the consent forms for all parts of the research. Data will be available following analysis, for 5 years after the study end date.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	14/10/2024	22/10/2024	No	Yes
Participant information sheet	version 4	18/12/2024	20/01/2025	No	Yes