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Lifestyle in Perimenopause: Exploring a Community Intervention

Submission date
21/10/2024

Recruitment status
No longer recruiting

Registration date
22/10/2024

Overall study status
Ongoing

Last Edited
20/01/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English Summary
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 August 2025. The study is expected to start recruiting in January 2025 and will run for 8 weeks initially, with follow-up questionnaires and a stakeholder meeting taking place around 6 months after the intervention.

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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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
349386

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

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 hypothesis
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

Study design
A single-centre mixed methods study

Primary study design
Observational

Secondary study design
Participatory action research

Study setting(s)
Charity/Voluntary sector

Study type(s)
Prevention, Quality of life

Participant information sheet

Condition
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 measure
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.

Secondary outcome measures
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.

Overall study start date
27/09/2021

Overall study end date
31/08/2025

Eligibility

Participant 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

Age group
Adult

Lower age limit
35 Years

Upper age limit
100 Years

Sex
Female

Target number of participants
12

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

Recruitment start date
09/12/2024

Recruitment end date
31/01/2025

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
The Health Agency
Wester Hailes Healthy Living Centre, 30 Harvesters Way
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Sponsor information

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Queen Margaret University

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Sponsor type
University/education

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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

Publication and dissemination plan
1. Publication is planned in a peer-reviewed journal.
2. Reports will be produced for the Health Agency, GP practices, Public Health Scotland, the Scottish Government Women's Health team, the ALLIANCE, and any other interested parties, including members of the public.
3. Artistic interpretations of the drawn timelines and body maps may be produced, and a fictionalised narrative may be produced for display and discussion.

Intention to publish date
31/08/2026

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