

An evaluation of an eight-session group-based, body-based autonomic regulation programme for menopausal symptoms: a pilot and feasibility study

Submission date 02/09/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 04/09/2026	Overall study status Completed	☒ Statistical analysis plan ☐ Results
Last Edited 07/09/2026	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Menopause can cause a range of physical and emotional symptoms, including hot flushes, sleep difficulties, anxiety, low mood, tiredness, and problems with memory and concentration. These symptoms can affect day-to-day life and wellbeing. Alongside medication-based treatments, there is growing interest in non-medication approaches that may help people manage menopausal symptoms.

This study looks at a new group-based programme designed to support regulation of the autonomic nervous system. This is the part of the nervous system that automatically helps control functions such as heart rate, breathing, and stress responses.

The programme combines education with practical techniques aimed at helping participants understand and regulate their physical and emotional responses. The main aim of this pilot and feasibility study is to find out whether the programme and study procedures are practical and acceptable to participants. The study also explores whether taking part in the programme is associated with changes in menopausal symptoms, sleep, everyday memory, anxiety and low mood compared with continuing usual care.

Who can participate?

Individuals assigned female at birth, aged 40-65. Those experiencing perimenopause or postmenopause can take part. Participants need to be experiencing menopausal symptoms and meet the study screening criteria, including a score of at least 12 on the Menopause Rating Scale. They also need to be able to attend the dates and times for one of the study groups, provide informed consent, and complete the study questionnaires.

Healthy volunteers without menopausal symptoms are not recruited.

What does the study involve?

Participants are randomly allocated to one of two groups. Around two-thirds of participants take

part in the eight-session group programme, while the remaining participants continue with their usual care during the study.

The programme is designed to support regulation of the autonomic nervous system and includes breathing practices, sleep education and strategies, controlled cold-water exposure, balance and movement exercises, exercises relating to the vagus nerve and primitive reflexes, and support with developing routines that work for each person. Later sessions also include group-led discussion around menopause, identity and sense of self.

Participants in the usual-care group do not receive the study programme during the main study period.

All participants complete questionnaires before the first session, at Session 6, at Session 8, and four weeks after Session 8. These questionnaires measure menopausal symptoms, sleep quality, everyday memory difficulties, anxiety and depressive symptoms. The study also records session attendance, adherence to exercises between sessions, participant retention and withdrawal, and anonymous feedback about how acceptable participants find the programme. Participants can also choose to wear an Ultrahuman Ring to collect sleep, activity and other body-related measurements. Wearing the ring is optional and is not required to take part in the study.

What are the possible benefits and risks of participating?

Participants may find the information, practical exercises and group discussions helpful in understanding or managing their menopausal symptoms and in developing strategies to support their wellbeing and regulation. Taking part also contributes information that may help researchers understand whether this type of programme is practical and suitable for testing in a larger study. Individual benefit cannot be guaranteed.

Some activities can cause temporary discomfort. Controlled cold-water exposure can feel uncomfortable, and some breathing, balance or movement exercises may feel unfamiliar. Discussions about menopause, wellbeing, identity or personal experiences can also bring up uncomfortable thoughts or emotions. All exercises are optional, and participants can raise concerns with the study team during or outside the sessions if preferred. Participants are not required to continue with an activity if they feel unable to do so.

Where is the study run from?

The Open Practice in Basingstoke, UK.

When is the study starting and how long is it expected to run for?

March 2026 to August 2026.

Who is funding the study?

There is no external funder. The study is funded internally by The Open Practice and its directors.

Who is the main contact?

Ben Allez, benallez@theopen-practice.co.uk

Contact information

Type(s)

Principal investigator, Public, Scientific

Contact name

Mr Ben Allez

ORCID ID

<https://orcid.org/0009-0008-9168-5821>

Contact details

The Open Practice,
Jameson House,
Lutyens Close
Basingstoke
United Kingdom
RG24 8AG
+44 7874846859
benallez@theopen-practice.co.uk

Additional identifiers

Study information

Scientific Title

A pilot randomised controlled feasibility study evaluating an eight-session group-based non-invasive intervention compared with treatment as usual for menopausal symptoms, sleep and psychological wellbeing in perimenopausal and postmenopausal participants

Study objectives

1. To assess the feasibility of delivering an eight-session, group-based, non-invasive intervention for perimenopausal and postmenopausal women experiencing menopausal symptoms
2. To assess the feasibility and acceptability of delivering an eight-session, group-based, non-invasive intervention for perimenopausal and postmenopausal participants experiencing menopausal symptoms
3. To explore preliminary changes in menopausal symptom severity associated with the intervention compared with treatment as usual
4. To explore preliminary changes in sleep quality, everyday memory difficulties, anxiety and depressive symptoms associated with the intervention compared with treatment as usual
5. To assess the feasibility of recruitment, cohort allocation, randomisation, retention, outcome-data collection and optional wearable monitoring procedures

Ethics approval required

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Ethics approval(s)

Approved 19/02/2026, Independent Research Ethics Committee (318 Old Laira Road, Plymouth, PL3 6AQ, United Kingdom; no telephone number provided; irec@justreasonable.org.uk), ref: IREC042

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Menopausal symptoms in perimenopausal and postmenopausal women, including vasomotor, psychological, sleep-related and somatic symptoms associated with the menopausal transition

Interventions

Participants are allocated in a 2:1 ratio to either the intervention group or a treatment-as-usual control group.

Randomisation is conducted separately for two cohorts of 18 participants. Cohort membership is determined before randomisation according to participants' ability to attend the specified intervention dates and times.

Within each cohort, eligible participants are stratified according to menopausal stage, classified as perimenopausal or postmenopausal. The number of participants allocated to the intervention within each stratum is calculated to approximate a 2:1 intervention-to-control allocation ratio, with minor adjustment where necessary to ensure that each cohort contains 12 intervention participants and six control participants.

Within each menopausal-stage stratum, intervention and control allocations are then randomly shuffled using the `sample()` function in R. Reproducibility is ensured by setting the random-number seed before allocation. The randomisation seeds correspond to the dates on which each cohort is randomised: `set.seed(03272026)` for Cohort 1, randomised on 27 March 2026, and `set.seed(04092026)` for Cohort 2, randomised on 9 April 2026.

Participants allocated to the intervention group receive an eight-session, group-based, non-invasive programme generally delivered approximately weekly. The overall calendar duration may vary slightly because of scheduling factors such as bank holidays.

The intervention combines psychoeducation with practical body-based and behavioural approaches intended to support autonomic regulation and the management of menopausal symptoms. Session content includes breathwork practices aimed at both calming and improving regulation; psychoeducation and practical strategies relating to sleep; controlled cold-water exposure; exploration of primitive reflex presentations; balance-based exercises; and vagus

nerve tract mobility exercises. Later sessions also include discussion around developing sustainable routines based on what works for each individual, alongside opportunities to reflect on identity and sense of self in relation to menopause with other members of the group.

Participants allocated to the control group continue with treatment as usual and do not receive the study intervention during the main study period.

Participants in both groups complete study outcome measures at baseline, at Session 6, at Session 8, and approximately four weeks after the final intervention session. These measures assess menopausal symptoms, sleep, psychological wellbeing and other health-related outcomes.

Participants may also opt to use an Ultrahuman Ring for wearable data collection. Participation in wearable monitoring is optional and is not required for enrolment in the study. The ring collects physiological, sleep, activity and related wearable-derived data. During the study period, participants are only able to view a limited set of core vital information within the Ultrahuman application and do not have access to their full wearable-derived data, including sleep-related information, until the study period has ended.

Intervention Type

Behavioural

Primary outcome(s)

1. Menopausal symptom severity measured using total score on the 11-item Menopause Rating Scale at baseline before session 1, session 6, session 8, and 4 weeks after session 8

Key secondary outcome(s)

1. Sleep quality measured using Pittsburgh Sleep Quality Index total score at baseline before session 1, session 6, session 8, and 4 weeks after session 8

2. Everyday memory difficulties measured using Everyday Memory Questionnaire – Revised total score at baseline before session 1, session 6, session 8, and 4 weeks after session 8

3. Anxiety symptoms measured using Generalized Anxiety Disorder 7-item scale total score at baseline before session 1, session 6, session 8, and 4 weeks after session 8

4. Depressive symptoms measured using Patient Health Questionnaire 9-item scale total score at baseline before session 1, session 6, session 8, and 4 weeks after session 8

5. Participant retention and attrition measured using Number and proportion of participants remaining in the study and completing scheduled follow-up assessments, with reasons for withdrawal recorded where provided at the 4-week follow-up, and throughout the intervention period

6. Intervention attendance measured using number and proportion of the eight scheduled intervention sessions attended by each intervention participant at sessions 1–8

7. Adherence to intervention practices measured using Participant-reported adherence to recommended between-session exercises and practices using short adherence forms at the start of sessions 2–8

8. Acceptability of the intervention measured using anonymous qualitative participant feedback regarding experiences of the intervention, perceived usefulness, barriers, and overall acceptability at following session 8

9. Feasibility of study procedures measured using recruitment, cohort allocation, randomisation, retention, completion of scheduled outcome assessments, and follow-up completion recorded from study records. at recruitment through 4-week follow-up

10. Feasibility of optional wearable data collection measured using uptake of optional Ultrahuman Ring participation, adherence to wearing the device, and completeness of wearable data collection among participants opting in at throughout the wearable monitoring period

Completion date

10/08/2026

Eligibility

Key inclusion criteria

1. Women and people assigned female at birth aged 40–65 years
2. Women experiencing perimenopause or postmenopause
3. Moderate-to-severe menopausal symptoms (MRS $\geq$ 12)

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

40 Years

Upper age limit

65 Years

Sex

Female

Total final enrolment

36

Key exclusion criteria

1. Major psychiatric or neurological disorders that could affect participation
2. Recent (<3 months) change in HRT or other menopause treatments
3. Any upcoming plans to change HRT or other menopause treatments (during study timeframe)
4. Inability to provide informed consent, complete assessments, or know they will miss more than one session

Date of first enrolment

12/03/2026

Date of final enrolment

10/04/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**The Open Practice**

Jameson House,

Lutyens Close

Basingstoke

England

RG24 8AG

Sponsor information

Organisation

The Open Practice

Funder(s)

Funder type**Funder Name**

The Open Practice

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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Protocol file	version 1.0	19/12/2025	04/09/2026	No	No
Statistical Analysis Plan	version 1.0	19/12/2025	04/09/2026	No	No