

Study Protocol and Statistical Analysis Plan

Title:

A Holistic Approach to the Management of Arterial Hypertension in Older Women: Evaluating the Effectiveness of a Mindfulness-Based Programme and the Forest Therapy Method

Brief title:

Mindfulness-Based and Forest Bathing Interventions for Older Women with Treated Arterial Hypertension

Document identifiers

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Study period: January 2025 – May 2025

Document date: 30 June 2026

Note on this document

This protocol was prepared on 30 June 2026 for the purpose of retrospective clinical trial registration. It describes the study as it was conducted between January and May 2025. This document contains no participant-identifying information.

1. Background and Rationale

Hypertension is highly prevalent among older women, in whom blood pressure control is influenced by chronic psychosocial stress and often deteriorates after menopause. Despite effective antihypertensive pharmacotherapy, blood pressure control at the population level remains suboptimal, creating a need for feasible, low-risk adjuncts to standard care that may support self-management and well-being without replacing medication.

Chronic psychosocial stress is increasingly recognised as a contributor to hypertension, and current European Society of Hypertension guidance acknowledges a role for stress-reduction approaches within lifestyle management. Two candidate adjunctive approaches are of particular interest: mindfulness-based interventions, which target attentional regulation, non-judgemental awareness and self-compassion; and forest bathing (Shinrin-yoku), a nature-based intervention thought to act through sensory immersion, attentional restoration, and parasympathetic activation. Comparative evidence on structured mindfulness-based versus forest-based adjuncts in older women with treated hypertension — assessed together across psychological, quality-of-life, and physiological outcomes — remains limited. This pilot study was designed to generate effect-size estimates to inform a future adequately powered trial rather than to provide confirmatory tests of effectiveness.

2. Objectives and Research Questions

2.1 General objective

To evaluate and compare the effectiveness of two adjunctive non-pharmacological interventions — an eight-week Mindfulness-Based Living Course (MBLC) and a guided forest bathing (Shinrin-yoku) intervention — relative to a non-randomised comparison group, in improving perceived stress, chronic-disease self-management self-efficacy, health-related quality of life, and selected physiological parameters among older women with treated arterial hypertension, from baseline to follow-up.

2.2 Research questions

- Does participation in MBLC or forest bathing result in a greater reduction in perceived stress from baseline to follow-up compared with the comparison group?
- Does participation in MBLC or forest bathing result in greater improvement in chronic-disease self-efficacy?
- Does participation in MBLC or forest bathing result in greater improvement in health-related quality of life (EQ-5D-5L and EQ-VAS)?
- Does participation in MBLC or forest bathing result in more favourable changes in physiological parameters (SBP, DBP, heart rate, cortisol)?
- Are there differences in effect between MBLC and forest bathing across psychological, quality-of-life, and physiological outcomes?

3. Study Design

Non-equivalent, pre-test/post-test quasi-experimental pilot study with three parallel groups (two intervention groups and one comparison group). Allocation was non-randomised: participants were assigned to groups pragmatically according to the geographical catchment of their general

practitioners (GPs) and community patronage nurses. The analytic aim was to estimate, for each outcome, whether the change over time differed by group.

Study type: Interventional

Allocation: Non-randomised

Intervention model: Parallel assignment (three groups)

Masking: None (open-label); outcome assessment was not blinded

Primary purpose: Supportive / adjunctive care; pilot effect-size estimation

4. Study Setting and Timeline

The study was conducted from January 2025 to May 2025 in Rijeka, Croatia. Recruitment was organised through participating GP practices and community patronage nurses serving populations from comparable urban neighbourhoods. Data were collected at two time points: T0 (baseline) and T1 (immediately after the intervention period). The primary completion date (final participant, final follow-up assessment for the outcomes analysed) was in May 2025.

5. Eligibility Criteria

5.1 Inclusion criteria

- Women older than 60 years;
- A diagnosis of arterial hypertension, pharmacologically treated;
- Signed informed consent to participate.

5.2 Exclusion criteria

- Age under 60 years;
- Inability to participate for the study duration (e.g., planned extended travel; terminal illness);
- Homelessness;
- A mental illness diagnosed according to DSM-5-TR;
- Cognitive impairment;
- Alcohol or other substance dependence;
- Absence of signed informed consent.

6. Interventions

6.1 Mindfulness-Based Living Course (MBLC)

An eight-week Mindfulness-Based Living Course delivered as one group workshop per week, each lasting approximately two hours. MBLC is a structured programme developed by the Mindfulness Association (United Kingdom) that cultivates present-moment awareness, compassion and self-compassion. Sessions progressed from attentional and somatic training toward emotion regulation and compassion-based capacities (Session 1: Start Where We Are; Session 2: The Body as a Place to Stay Present; Session 3: Introducing Mindfulness Support; Session 4: Working with Distraction; Session 5: Exploring the Undercurrent; Session 6: Attitude of the Observer; Session 7: Self-acceptance; Session 8: A Mindfulness-Based Life). Workshops were led by trained, certified mindfulness facilitators using

a structured manual. Participants were encouraged to undertake daily home practice of approximately 20–30 minutes, supported by audio/video-guided exercises and a workbook; home-practice adherence was not formally tracked.

6.2 Guided Forest bathing (Shinrin-yoku)

Three structured forest bathing sessions lasted approximately 120–150 minutes and was scheduled once weekly within the 09:00–11:30 window to limit diurnal variation in physiological outcomes, particularly cortisol. The same site and predefined route (approximately 1.5–2 km) were used for all sessions. Sessions were led by a certified Forest Bathing guide accredited by the Forest Therapy Hub (FTHub) and followed the FTHub Walk Activities Sequence (introduction/arrival; Mechanical Senses; Chemical Senses; Engage/Direct Exposure activities; Txoko sit-spot; closing Circle of Incorporation). No structured home practice was assigned between sessions.

6.3 Comparison group

The comparison group continued usual care and daily activities and did not participate in the mindfulness or forest bathing sessions.

7. Outcome Measures

All outcomes were assessed at baseline (T0) and immediately post-intervention (T1). Consistent with the pilot research, effect-size-estimation purpose of the study, a single primary outcome was designated on mechanistic grounds (perceived stress is the proximal target common to both interventions); all remaining outcomes are designated secondary and are interpreted as exploratory.

7.1 Primary outcome

- Perceived stress, measured by the 10-item Perceived Stress Scale (PSS-10). Time frame: change from T0 to T1. Higher scores indicate greater perceived stress.

7.2 Secondary outcomes

- Chronic-disease self-management self-efficacy — Self-Efficacy for Managing Chronic Diseases 6-item Scale (SEMCD-6); change T0→T1.
- Health-related quality of life — EQ-5D-5L index; change T0→T1.
- Self-rated health — EQ visual analogue scale (EQ-VAS, 0–100); change T0→T1.
- Systolic blood pressure (SBP), mmHg — validated monitor (Microlife BP B3 AFIB), mean of three seated measurements after 5 minutes' rest; change T0→T1.
- Diastolic blood pressure (DBP), mmHg — same procedure; change T0→T1.
- Heart rate, bpm — same device; change T0→T1.
- Serum cortisol, nmol/L — venous sampling between 08:00–09:00, fasting, single laboratory (Analiza Clinic, Rijeka); change T0→T1.

8. Sample Size and Power

Given the community-based nature of this pilot, sample size was determined by participant availability and community capacity rather than a prospective power calculation; the purpose was to generate effect-size estimates.

9. Statistical Analysis Plan

9.1 Software and analysis population

All analyses will be performed in IBM SPSS Statistics v28.0. The analysis population will comprise all participants who completed both the baseline (T0) and follow-up (T1) assessments for the outcome in question (complete-case analysis).

9.2 Descriptive statistics

Continuous variables will be summarised as means and standard deviations; categorical variables as counts and percentages.

9.3 Baseline comparability

Baseline differences between the three groups will be assessed using the chi-square test for categorical/dichotomous variables and the Kruskal–Wallis test for ordinal variables.

9.4 Primary analysis

The primary outcome was perceived stress (PSS-10). The change from T0 to T1 across groups will be assessed using a two-way repeated-measures analysis of variance (group $\times$ time). The group $\times$ time interaction will be the effect of interest. The post hoc Tukey Honestly Significant Difference (HSD) procedure will be used to control the family-wise error rate across the pairwise comparisons within this analysis.

9.5 Secondary and exploratory analyses

Each secondary outcome (SEMCD-6; EQ-5D-5L index; EQ-VAS; systolic and diastolic blood pressure; heart rate; serum cortisol) will be analysed with the same two-way repeated-measures ANOVA (group $\times$ time) and Tukey HSD procedure.

10. Ethical Considerations

The study was conducted in accordance with the Declaration of Helsinki and the Nuremberg Code, the Croatian Health Act and Act on the Rights of Patients, and Regulation (EU) 2016/679 (GDPR). It was approved by the Ethics Committee of the University of Rijeka, Faculty of Medicine (Class: 007-08/24-01/70; Reg. no.: 2170-1-42-04-3/1-24-12) on 22 October 2024. All participants provided written informed consent.