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Controlled assessment of landscape-based mindfulness - forest for health

Submission date
24/04/2025

Recruitment status
Recruiting

Registration date
15/05/2025

Overall study status
Ongoing

Last Edited
13/05/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Spending time in nature can reduce stress, improve mood, and enhance cognitive function. Exposure to natural environments such as forests (as in forest bathing and therapy) can lead to decreased cortisol levels, lower blood pressure, and increased feelings of relaxation and happiness. Nature-based therapies (NBTs) are also linked to increased social interactions, which can lead to increased sense of belonging, decreased isolation and – consequently – potentially lower levels of experienced marginalization. Moreover, the increased skills development and confidence resulting from NBTs may increase self-efficacy and resilience, even when faced with discrimination.

While forest bathing shows promise for improving mental health, evidence supporting its effectiveness is still limited. Many existing studies suffer from small sample sizes, lack of control groups, unclear intervention protocols, and reliance on short-term outcomes. Additionally, research often lacks consistency in measures and fails to explore differences across population subgroups or pathways through which NBTs impact mental health.

Importantly, no study has directly assessed whether NBTs can reduce perceived discrimination, marginalization, or stigmatization—key factors that affect mental well-being. Therefore, research on this specific relationship is needed. Given the fact that NBTs can enhance overall mental health, it is plausible that NBTs might also mitigate negative effects associated with perceived discrimination and/or stigmatization. With the growing interest in NBTs worldwide, there is a clear need for more robust research, particularly in health economics, to assess both the costs and health outcomes of these interventions.

To date, no studies have combined cost-effectiveness with health outcomes for NBTs. Given the resource constraints in public health, conducting such evaluations alongside clinical trials is crucial for informing policy decisions. This study aims to fill these gaps by evaluating the impact of NBTs on perceived stress and discrimination while also assessing their cost-effectiveness. This study aims to evaluate the effectiveness of a guided forest bathing program in reducing perceived stress compared to usual care.

Who can participate?
Adult patients aged 18–64 years for whom stress interference in daily life is significant or very significant.

What does the study involve?
The guided forest bathing program in the Stockholm area, in urban forests in Sweden, also being studied in Barcelona, involves a 12-week Nature-Based Stress Therapy (NBST) intervention in urban and peri-urban forests of Stockholm. Participants, grouped in 8-12 with a guide and assistant, attend weekly 120-minute sessions. The program, using the Eco Forest Therapy structure, is divided into two parts: the first 6 weeks focus on stress reduction, rest, and recovery, while the latter 6 weeks incorporate nature activities and social sharing. The NBST progresses through four phases: stress reduction and rest (sessions 1-3), recovery and connectedness (sessions 4-6), nature activities and coherence (sessions 7-9), and integration with nature-based self-care (sessions 10-12). Allocation to the program is done via computer-generated pseudorandom numbers.

What are the possible benefits and risks of participating?
No benefits or risks provided at registration

Where is the study run from?
Swedish University of Agricultural Sciences

When is the study starting and how long is it expected to run for?
October 2024 to December 2026

Who is funding the study?
The European Union’s Horizon Europe Research and Innovation Programme

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
European Union’s Horizon Europe Research and Innovation Programme Grant Agreement No. 101084198.

Study information

Scientific Title
The impact of forest bathing on stress reduction: a randomized control trial

Acronym
CALM

Study objectives
A guided forest bathing program in Sweden is more effective in reducing perceived stress compared to usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/04/2025, Ethics Review Authority (Etikprövningsmyndigheten) (Box 2110, Uppsala, 750 02, Sweden; +46 010-475 08 00; registrator@etikprovning.se), ref: Dnr 2025-01954-01

Study design
Prospective two-armed interventional randomized controlled study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Stress interference in daily life being significant or very significant; ICD diagnoses: F43.8a (primary), F32.0, F32.1, F41.0 (secondary).

Interventions
Guided forestbathing - mindfulness in Sweden. A similar study design is being conducted by collaborators in Barcelona, Spain.

Computer-generated allocation by software: Sealed Envelope (pseudorandom number generator)

Intervention Programme: Forest bathing program as an example of NBI
Location: Urban and peri-urban forested areas, Stockholm
Methodology: Nature-Based Stress Therapy (NBST)
Intervention model: A closed group-based intervention.
Group size: 8-12 participants, one guide and one assistant
Duration of programme: 12 consecutive weeks/one session each week for 120 minutes at a time.
Frequency sessions: 1 session/week
Duration of each session: 120 minutes/session

The two parts of NBST: The programme offers a gradual process, from stress reduction and recovery to the maintenance of a nature-based self-care. All sessions follow the same Eco Forest Therapy structure, but with additions tailored to support stress-related ill health.

1. 6 weeks targeting mainly stress reduction, rest and recovery
2. 6 weeks adding nature activities and social sharing

The 4 phases of NBST: The four phases of NBST are the intended treatment progression of the programme. For each phase, particular focuses or themes are introduced, as guidelines for the choice, pacing and energy level of activities. These are seamlessly integrated into the (Eco Forest Therapy) methodological structure, invisible to the participant, but a key function for the guide.
Session 1-3: Stress reduction and rest
Session 4-6: Recovery, connectedness and attachment
Session 7-9: Nature -activities, relation and coherence
Session 10-12: Integration, nature-based social sharing and the maintenance of nature-based self-care

Intervention Type
Behavioural

Primary outcome(s)
Perceived stress measured using the Perceived Stress Scale at baseline, at the end of the intervention (FU1), 4 weeks (FU2) and 12 weeks (FU3) after the intervention

Key secondary outcome(s))
The secondary outcome measures were assessed at baseline, at the end of the intervention (FU1), 4 weeks (FU2) and 12 weeks (FU3) after the intervention, unless other stated:
Health measures:
1. Stress measured using the Perceived Stress Scale (10 items) or the self-developed question in the screening questionnaire
2. Quality of Life measured using the EuroQol 5 Dimensions 5 levels (EQ-5D-5L) 5 items and general health reported on a visual scale from 0 to 100
3. Wellbeing measured using the ONS-4 (4 items)
4. Wellbeing (Optional) measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) 14 or 7 items
5. Anxiety (Optional) measured using the Generalized Anxiety Disorder-7 (GAD-7) 7-item self-reported questionnaire
6. Sleep Quality (Optional) measured using the PSQI-2
7. Emotional Regulation (Optional) measured using the Difficulties in Emotion Regulation Scale (DERS-16)
8. Self-Esteem (Optional) measured using the Rosenberg Self-Esteem Scale (RSES) 10-item scale
9. Depression (Optional) measured using the Patient Health Questionnaire-9 (PHQ-9)

10. Psychological Distress (Optional) measured using the Kessler Psychological Distress Scale (K10)
11. Complicated Grief (Optional) measured using the Inventory of Complicated Grief (ICG)

Cost-utility data:
13. User satisfaction (Optional) measured using the self-reported questionnaire Adapted version of the Client Service Receipt Inventory (CSRI) at baseline and FU3

Pathways:
14. Human-Nature connectedness (Optional) measured using the self-reported questionnaire introduced by "The following questions are about you and nature. By nature, we mean all types of natural environment and all the plants and animals living in them. Nature can be close to where you live in towns, the countryside, or wilderness areas further away." at baseline and FU1
15. Perceived health benefits from exposure to nature (Optional) measured using the phone questionnaire (to link with WP4) at baseline and FU3
16. Subjective biodiversity (Optional; adapted to each NBT type) measured using the phone questionnaire (Fuller et al, 2007) at FU1

Covariates:
17. Gender (basic question, only male/female/non-binary/other/prefer not to answer) measured using the phone questionnaire at screening
18. Gender (including transgender, i.e. first asking about sex, then asking about gender) measured using the face-to-face method at FU1
19. Age measured using the phone questionnaire or face-to-face method at screening
20. Ethnicity/Race (to be defined according to what is culturally/socially accepted in each country) measured using the self-administered questionnaire at baseline
21. Experiences of discrimination (long) measured using the self-administered questionnaire at baseline
22. Stigmatisation experiences measured using the Inventory of Stigmatising Experiences (ISE) at baseline, FU1, FU2, FU3
23. Discrimination measured using the Everyday Discrimination Scale (EDS) at baseline, FU1, FU2, FU3
24. Highest education level completed measured using the self-administered questionnaire at baseline
25. Perceived Income measured using the self-administered questionnaire at baseline
26. Sexual orientation (Optional) measured using the self-administered questionnaire at baseline
27. Medication intake (indirect question specifically related to the health outcomes) measured using the self-administered questionnaire and phone questionnaire at FU1, FU2
28. Exposure to different levels of green care measured using the phone questionnaire or self-administered questionnaire (to differentiate between NEL, NBP, NBT) at baseline, FU1, FU2, FU3
29. Expected treatment (1 item) (Optional) measured at FU1, FU2, FU3
30. Activities done measured using closed-ended answers based on the description that each intervention has shared with us at FU1, FU2, FU3

Completion date
31/12/2026

Eligibility

Key inclusion criteria

1. Age 18–64 years
2. Stress interference in daily life is significant or very significant; ICD diagnoses: F43.8a (primary), F32.0, F32.1, F41.0 (secondary)
3. Ability to understand the information for participation in the study and the forest bathing intervention, both by oral and written instructions
4. Signed Content, protocol compliance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
64 years

Sex
All

Key exclusion criteria
1. Intellectual disability, phobias, dissociative behaviours (ICD-11 codes)
2. Conditions preventing participation or intervention suitability
3. Participated in any kind of NBI in the last 12 months
4. MB23.0 - aggressive behaviour
5. Suicidal risks, known drug or alcohol abuse, evaluated by referring MD

Date of first enrolment
01/05/2025

Date of final enrolment
01/04/2026

Locations

Countries of recruitment
Sweden

Study participating centre
Swedish University of Agricultural Sciences
Slottsvägen 5

Lomma
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23422

Sponsor information

Organisation
European Union’s Horizon Europe Research and Innovation Programme

Funder(s)

Funder type
Not defined

Funder Name
Horizon Europe Research and Innovation Programme

Results and Publications

Individual participant data (IPD) sharing plan
All study data will be securely stored in the project’s cloud-based storage system (Microsoft Teams-UAB-GreenM under the lead Margarita Triguero-Mas). Database templates in Qualtrics are country-specific data sets; see above outcome measurements for Sweden. No data will be saved on local desktop computers or laptops at the country level. The completion of the T3.3 dataset will be made available on the GreenME website upon request by contacting the lead, M. Triguero-Mas.

Two years after the conclusion of the GreenME project or after the primary publications are released, processed, anonymized, and aggregated data (along with corresponding metadata) will be deposited in a trusted repository, such as ddd.uab.cat, dmp.csuc.cat, or zenodo.org. The data will be shared in standard formats (.csv, .doc, .pdf, .jpg, .txt), and a Digital Object Identifier (DOI) will be assigned to the dataset. Metadata will be created following the Dublin Core standard, including relevant keywords from an established thesaurus (e.g., MESH terms) to ensure discoverability.

The UAB ethics committee will review all data storage and access procedures before publication. Data will be retained and accessible for a minimum of five years following the completion of the study. An external drive will be used to create a security copy of all the project documents each month. The external memory will be kept in a locked physical place at UAB, which location will only be known by a very small group of people (approximately 4 people, including the 2 scientific coordinators of the project).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet		28/04/2025	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file	Study website	13/03/2025	28/04/2025	No	No
Study website		11/11/2025	11/11/2025	No	Yes