ISRCTN10469927 https://doi.org/10.1186/ISRCTN10469927

Can a 6-day guided hiking and mindfulness programme in biodiverse Alpine landscapes improve wellbeing and reduce rumination in older adults?

Submission date
27/04/2026

Recruitment status
No longer recruiting

Registration date
07/05/2026

Overall study status
Ongoing

Last Edited
06/05/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Stress, poor sleep, and repeated negative thinking can have a major effect on health in older age. Many older adults experience rumination, which means getting stuck in repetitive thoughts or worries. Nature-based therapies may help reduce stress and improve well-being, but it is still unclear whether biodiversity, meaning the richness and variety of plants and animals in an environment, adds extra health benefits. The aim of this study is to find out whether a structured six-day nature-based therapy programme in biodiverse Alpine environments can improve psychological well-being, reduce rumination, and support better physiological stress regulation in older adults. The study also looks at sleep, resilience, and nature connectedness.

Who can participate?
Adults aged 60 to 75 years can take part if they have elevated rumination, are able to live independently, have a chronic non-immunological condition such as osteoporosis or controlled hypertension, and are physically able to complete light hiking tours of 3 to 6 hours with 300 to 600 metres of elevation gain.

What does the study involve?
The study plans to include 80 participants, with 40 people in the intervention group and 40 in the control group. Participants are randomly assigned to one of the two groups. The intervention group takes part in a six-day Nature-Based Therapy programme in the Lungau Biosphere Reserve in Austria. This includes guided hikes of at least 4 hours per day in alternating high- and low-biodiversity areas, plus 30 to 60 minutes of guided nature-based mindfulness training during the hikes. During the intervention week, participants in the intervention group also complete short questionnaires before and after each guided hike using the MyCap mobile app.
All participants are followed for 90 days. At the start of the study, baseline assessments are carried out. For the intervention group, these take place at the study site and include psychological, physiological, and biological measurements. For the control group, baseline

questionnaires and saliva samples are collected online by self-sampling. After the six-day intervention, the intervention group completes post-intervention testing. At 30 days and 90 days, both groups complete online questionnaire assessments and saliva self-sampling. The control group does not receive the guided nature-based therapy during the study period, but after the final follow-up they are offered a weekend stay in the Lungau Biosphere Park without intervention.

What are the possible benefits and risks of participating?
Participants may benefit from the programme through improved well-being, less rumination, better sleep, and improved stress regulation, although this cannot be guaranteed. Because the study involves light hiking, there is physical effort involved. To reduce risk, only people who are physically able to complete light hikes are included, and people with medical conditions that could make participation unsafe are excluded. Participants are informed in writing and verbally about the study procedures and potential risks before they give consent. Any unexpected or adverse events are documented and reported to the Ethics Committee. Participants may withdraw from the study at any time without giving a reason.

Where is the study run from?
The study is run by the Institute of Ecomedicine at Paracelsus Medical University Salzburg, Austria. The intervention takes place in the UNESCO Biosphere Reserve Lungau, Austria.

When is the study starting and how long is it expected to run for?
Recruitment begins after ethics approval. The intervention is planned in two rounds in May 2026. Each participant takes part for about 3 months, including baseline assessment, the six-day intervention period, and follow-up assessments at 30 and 90 days. The final follow-up assessments are planned for August 2026.

Who is funding the study?
The study is funded through Interreg VI-A Italien–Österreich as part of the EU Interreg CONNATURALP project.

Who is the main contact?
Barbara Fixl, MSc. BA., Institute of Ecomedicine, Paracelsus Medical University, barbara.fixl@pmu.ac.at

Contact information

Type(s)
Principal investigator, Public

Contact name
Ms Barbara Fixl

ORCID ID
https://orcid.org/0009-0007-1183-6419

Contact details
Strubergasse 22, Haus C (1. OG)
Salzburg
Austria
5020

+43 662 242080542
barbara.fixl@pmu.ac.at

Type(s)
Scientific, Public

Contact name
Dr Arnulf Hartl

ORCID ID
https://orcid.org/0000-0001-9626-6425

Contact details
Strubergasse 22, Haus C (1. OG)
Salzburg
Austria
5020
+4369914420022
arnulf.hartl@pmu.ac.at

Additional identifiers

Study information

Scientific Title
A single-centre, two-arm, randomized controlled clinical field trial evaluating a 6-day nature-based therapy programme delivered in biodiverse Alpine environments versus usual-life control on rumination, psychological wellbeing and allostatic load in adults aged 60–75 years with elevated rumination.

Acronym
CONNATURALP

Study objectives
1) To determine whether a six-day Nature-Based Therapy intervention in biodiverse Alpine environments reduces rumination and improves psychological well-being in older adults aged 60–75 years compared with control.
2) To determine whether the intervention improves physiological regulation, assessed by Allostatic Load Index Salivary (ALI-S), compared with control.
3) To assess effects on sleep quality, life evaluation/anxiety-worry, biopsychosocial resilience, and nature connectedness.
4) To explore mediators, moderators, and maintenance of effects at 30 and 90 days.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/02/2026, Institutional PMU Ethics Committee (Strubergasse 21, Salzburg, 5020, Austria; +43 662 2420-80356; ethik.kommission@pmu.ac.at), ref: PMU-EK-2025-0069

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Prevention, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Stress-related conditions in older adults with elevated rumination

Interventions
Participants are randomly assigned in a 1:1 ratio to either the intervention arm or the control arm. Randomization is performed by an independent biometrician using an open-source add-in for Microsoft Excel, with age and gender used as stratification factors and the Kullback-Leibler divergence method used for allocation. The intervention arm receives a six-day Nature-Based Therapy (NbT) programme in the UNESCO Biosphere Reserve Lungau, Austria. NbT consists of green exercise/hiking and nature-based mindfulness training. Participants complete guided hikes of at least 4 hours per day on alternating days in high- and low-biodiversity areas; each hike covers 2–7 km with up to 500 m elevation gain, and groups include up to 16 participants accompanied by at least one trained hiking guide. During these hikes, participants receive 30–60 minutes of nature-based mindfulness training based on concentrative movement therapy in a pre-selected restorative and safe location. Intervention sessions are documented using the MyCap mobile application, including BIO-WELL and the CONNATURALP Nature-based Intervention Questionnaire.

All participants are followed for 90 days with four main measurement points. At T0 (day 0), baseline assessment is performed before the intervention. In the intervention arm, this includes psychological, physiological and biological assessments at the study site, including saliva sampling; in the control arm, questionnaires and saliva samples are collected online by self-sampling with freezing of the sample. At T1 (day 6), only the intervention arm undergoes post-intervention assessment at the study site, with testing identical to T0. At T2 (day 30) and T3 (day 90), all participants in both arms complete online questionnaire assessments and saliva self-sampling. Primary and secondary questionnaire outcomes include rumination (RRS), psychological well-being (WHO-5), sleep quality (PSQI), life evaluation/anxiety-worry (ONS-4), biopsychosocial resilience (CRS), and nature connectedness (NCI). Physiological outcomes include the Allostatic Load Index Salivary (ALI-S), comprising heart rate variability, blood pressure, peak expiratory flow, salivary IL-6/IL-10, and salivary cortisol/DHEA-S.

The control arm receives no treatment during the intervention period and continues usual life without guided nature sessions. For ethical reasons, control participants are offered a weekend stay in the Lungau Biosphere Park without intervention after the final examination at day 90.

Intervention Type
Other

Primary outcome(s)
1. Rumination measured using the Ruminative Responses Scale (RRS) - 10 at T0 baseline (day 0), T1 post-intervention (day 6), T2 follow-up 1 (day 30), and T3 follow-up 2 (day 90)

2. Psychological well-being measured using the WHO-5 Well-Being Index at T0 baseline (day 0), T1 post-intervention (day 6), T2 follow-up 1 (day 30), and T3 follow-up 2 (day 90)

3. Physiological regulation / allostatic load measured using heart rate variability (HRV; RMSSD, HF-band), measured using the Polar Vantage V3 watch, with recording and analysis in Kubios HRV (Premium), including artefact correction; blood pressure (BP), measured using the Omron Healthcare M400 Intelli IT; peak expiratory flow (PEF), measured using a peak flow meter; salivary interleukin-6/interleukin-10 (IL-6/IL-10), measured using Salimetrics kits; and salivary cortisol/dehydroepiandrosterone sulfate (cortisol/DHEA-S), measured using Salimetrics kits, at T0 baseline (day 0), T1 post-intervention (day 6), T2 follow-up 1 (day 30), and T3 follow-up 2 (day 90)

Key secondary outcome(s)
1. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at T0 baseline (day 0), T1 post-intervention (day 6), T2 follow-up 1 (day 30), and T3 follow-up 2 (day 90)

2. Life evaluation / anxiety-worry measured using the ONS-4 core module at T0 baseline (day 0), T1 post-intervention (day 6), T2 follow-up 1 (day 30), and T3 follow-up 2 (day 90)

3. Biopsychosocial resilience measured using the Comprehensive Resilience Scale (CRS) at T0 baseline (day 0), T1 post-intervention (day 6), T2 follow-up 1 (day 30), and T3 follow-up 2 (day 90)

4. Nature connectedness measured using the Nature Connectedness Index (NCI) at T0 baseline (day 0), T1 post-intervention (day 6), T2 follow-up 1 (day 30), and T3 follow-up 2 (day 90)

Completion date
15/08/2026

Eligibility

Key inclusion criteria
1. Age between 60 and 75 years
2. Elevated rumination according to the Ruminative Response Scale (RRS-10)
3. Physical ability for light hiking tours (duration 3–6 hours; elevation gain 300–600 meters/day)
4. Ability to live independently

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
60 years

Upper age limit
75 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Uncontrolled hypertension (≥180/≥100 mmHg)
2. Abnormal blood glucose levels: fasting ≥140 mg/dl or <70 mg/dl, or non-fasting >200 mg/dl
3. Renal insufficiency (serum creatinine >2.0)
4. Malnutrition (serum albumin <3.2 g/l)
5. Anemia (hematocrit <30%)
6. Inflammatory or infectious diseases (leukocytes <1500/ml^3)
7. Thyroid disorders (TSH <0.3 or >4.0 mU/l)
8. Cognitive impairments (Mini Mental Status <23)
9. Orthopedic limitations preventing hiking
10. Acute pain
11. Chronic immunological diseases (e.g. rheumatoid arthritis, Crohn's disease, pathological immune disorders)
12. Severe respiratory diseases requiring oxygen
13. Malignant tumors (treatment within the last 5 years)
14. Arteriosclerotic event <2 months before study start
15. Heart failure (LVEF <50%)
16. Alcohol/drug abuse, smoking >10 cigarettes/day
17. Immunosuppressive therapy (e.g. prednisolone, Imuran, methotrexate, monoclonal antibodies such as Tacrolimus or Everolimus)

Date of first enrolment
01/03/2026

Date of final enrolment
04/05/2026

Locations

Countries of recruitment
Austria

Sponsor information

Organisation
Paracelsus Medical University

ROR
https://ror.org/03z3mg085

Funder(s)

Funder type

Funder Name
Interreg

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
1) De-identified individual participant data generated during and/or analysed during the current study will be stored in a publicly available repository. In line with the FAIR Guiding Principles, CONNATURALP will share and archive data on the Open Science Framework (OSF) as the primary repository. To promote findability and facilitate dissemination within the wider nature-based solutions community, information on the results and links to datasets will also be shared via OPPLA, the EU repository for Nature-Based Solutions. The data to be shared will include de-identified quantitative participant-level data underlying the primary and key secondary outcomes of the study, including questionnaire-based and physiological outcome measures, as appropriate. The data will be made available after publication of the main study results in peer-reviewed journals and in accordance with applicable ethical and legal requirements. Written consent for the use and sharing of personal data will be obtained from all study participants. Each participant will be assigned a six-digit identification number (ID) for anonymisation purposes. Personal data will only be stored in ID-encrypted form. The password-protected master list linking IDs to personal data will be stored on a secure data server at the Paracelsus Medical University of Salzburg and will be accessible only to the researcher responsible for recruitment, eligibility checks and allocation. The master list linking participant names and study IDs will be deleted before the study data are published.

2) De-identified individual participant data generated during and/or analysed during the current study may also be made available upon reasonable request from Barbara Fixl, MSc., Paracelsus Medical University Salzburg, Institute of Ecomedicine, Strubergasse 22, 5020 Salzburg, Austria,

barbara.fixl@pmu.ac.at. Data access will be subject to applicable ethical approval, participant consent, data protection requirements, and institutional procedures.

3) Publications and dissemination activities arising from the study will respect the protection of personal data. Where appropriate, de-identified datasets may also be published as supplementary material alongside the main results publication, depending on journal policies and suitability.

IPD sharing plan summary

Available on request, Stored in publicly available repository