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Integrating environmental and skill-based approaches to health and resilience: A case study within the European research collaboration RESONATE.

Submission date
23/04/2024

Recruitment status
Recruiting

Registration date
29/05/2024

Overall study status
Ongoing

Last Edited
28/05/2025

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
The escalating mental health crisis is largely driven by increasing numbers affected by mild to moderate symptoms of depression, anxiety and stress. Without treatment, such common mental health symptoms may have chronic consequences in personal life (e.g., social withdrawal, poor health habits) and on the labour market (e.g., poor performance and increased drop-out from higher education), and threaten physical health through multiple pathways. However, the accessibility and effectiveness of conventional health care is limited for this large group.
Among the possible causes of the mental health crisis, scholars have particularly pointed to major social, technological, cultural, and economic changes that exert adaptation pressures on individuals, communities and ecosystems. At a nexus of these interconnected trends, global urbanisation shows staggering increase from fewer than 1 billion people living in urban areas in 1950 to more than 6.5 billion projected by 2050. Common concerns include chronic stress, low physical activity, social disconnectedness and poor opportunities for contact with nature – each factor associated with low resilience and long-term health risks.
Nature-based therapies (NbT) structure various activities and experiences in natural environments to achieve defined treatment goals. They span from undemanding leisure activities in green prescriptions to targeted programs that integrate nature-based activities with conventional therapeutic techniques – mindfulness practice being among the most common – to address specified health processes. They also commonly build supportive person-group and person-environment connections that can help generalize resilience outcomes to community and ecosystem levels.
The study compares two NbT's – a green prescription without conventional therapeutic components and an integrated nature- and mindfulness-based intervention – with each other, with a conventional mindfulness-based intervention completed indoors, and with a wait list control condition. It aims to:
1. determine whether the two NbT's are attended by symptom severity reductions compared to waitlist, defined as average reduction in ratings of psychological distress (the main outcome) and defined as proportions of participants who show reliable improvements in psychological

distress;
2. map how the nature- and mindfulness-based treatment components alone and in combination contribute to a range of health and resilience-related secondary outcomes;
3. understand how activities and experiences in connection with the respective group meetings and homework assignments shape participant's engagement with the interventions.

Who can participate?
In many countries including Sweden, university students have elevated risk of common mental health symptoms that threaten the major personal and societal investments in education of young generations. We plan to let 260 Swedish university students, aged 18-40 and approximately balanced between females and males, go through the interventions. We will recruit volunteers who are motivated to participate in such interventions. We will assess their mental health status and equally divide those with minimal or mild and those with moderate psychological distress between the four treatment arms. Participants with severe disorders will be excluded.

What does the study involve?
The participants will be randomly assigned between:
1. Green prescription: a nature-based program with meaningful outdoor activities but no conventional therapeutic components.
2. Restoration skills training: a nature- and mindfulness-based program that integrates environmental and skill-building mental health practices.
3. Conventional mindfulness training: a mindfulness-based program with skill-building mental health practices but no nature-based components.
4. Wait list: a passive condition where the intervention start is delayed until programs 1-3 and associated assessments are completed.

The study is thus factorial in that it contrasts the two factors Nature-based (yes/no) and Mindfulness-based (yes/no). The active interventions have one group meeting per week over five weeks and 20-min daily homework assignments.

Before, directly after, five weeks after and six months after the interventions, we will obtain self-reports of:
• Psychological distress
• Health-related quality of life
• Psychological resilience
• Cognitive functioning
• Trait mindfulness
• Social loneliness
• Nature habits
• Trait nature connection
• Environmental concerns
• Pro-environmental behavior
• Value-orientation
• Health care service use
• Intervention acceptability (not included in the follow-up assessments)

In connection with the group meetings, we will obtain self-reports of:
• Perceived restorative qualities in the environment
• State mindfulness
• State nature connection
• Intervention group environment

• Physical activity in the preceding week
• Completed homework assignments in the preceding week

What are the possible benefits and risks of participating?
The three active interventions are all provided in good faith. They are founded in broadly accepted treatment principles and have direct or indirect support in previous research, and will be delivered by instructors with suitable training and experience with the intention to help improve participant's mental health and resilience. Our screening procedures will exclude volunteers who based on best-practice recommendations may be at elevated risk for serious adverse events due to current severe mental health symptoms, suicidal ideation or self-harm; current or previous psychotic or bipolar symptoms; or moderate to severe allergies that can be triggered in nature visits. We will mitigate other risks by using professional instructors with suitable training who will provide appropriate advice and guidance for the intervention activities, for instance in how participants should check themselves for ticks after nature-based activities and how they can modify mindfulness practices that trigger anxiety. However, we do expect that some participants will experience different transient discomforts in connection with nature visits (e.g., due to unpleasant weather) and mindfulness exercises (e.g., restlessness).

Where is the study run from?
Uppsala University, Institute for Housing and Urban Research (Sweden)

When is the study starting and how long is it expected to run for?
November 2020 to December 2025.

Who is funding the study?
The study is part of the RESONATE project which is funded by the European Union's Horizon Europe Research and Innovation programme grant 101081420 and UK Research and Innovation grant 10063874.

Who is the main contact?
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Study website
https://resonate-horizon.eu/case-study-7-level-3/

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Randomized controlled trial comparing nature-based, mindfulness-based and combined interventions and a wait list control for common mental health symptoms and promotion of psychological and social-ecological resilience in young adults

Acronym
RESONATE case study 7

Study objectives
The study compares three health interventions - a green prescription (nature-based), a conventional mindfulness course (mindfulness-based) and an integrated nature- and mindfulness-based course - to each other and to a wait list condition. For the main outcome, psychological distress, we hypothesize that the nature-based and integrated interventions will be attended by significant improvement on average. Such findings would help fill the gap of robust clinical evidence for the utility of structured nature-based mental health interventions. Additional aims of the study will be fulfilled by analyzing several secondary outcomes and process measures to map and contrast potential mechanisms and resilience-related co-benefits of the nature- and mindfulness-based treatment components alone and in combination.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/03/2024, Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46 104750800; registrator@etikprovning.se), ref: 2021-06675-01 (original application); 2024-01087-02 (addendum)

Study design
Non-blinded single-center four-armed factorial randomized parallel and wait list controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community, Home, Other

Study type(s)
Prevention, Quality of life, Treatment

Participant information sheet
Not available in public web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Common mental health symptoms, including mild to moderate depression, anxiety, stress and general psychological distress.

Interventions
The study involves random assignment with equal likelihood between a wait list condition and three active interventions. The active interventions all span five weeks with one instructor-led 2-hour group meeting (with up to 12 participants) per week and 20-minute homework assignments to be completed independently once per day. Each intervention is framed as an introductory course and explicitly aimed at establishing basic understandings and habits that participants can then continue to develop independently. The Green Prescription and Conventional mindfulness interventions will be delivered by hired professionals with specific training and experience in delivering the respective interventions and without previous affiliation to the project. The integrated nature- and mindfulness-based intervention that was developed by the researchers will be delivered by instructors trained by the researchers as part of the project. The researchers will monitor the instructors' fidelity to the planned interventions as well as their adaptations to unforeseen constraints and emerging needs. The interventions will be provided as a complement to any other care that participants take part in and so will not replace any regular treatment.

The integrated nature- and mindfulness-based intervention builds on a program called Restoration Skills Training (ReST): a theoretical framework and treatment protocol that was developed over 10 years by members of the research group (unpublished protocol; see Lymeus, 2019; Lymeus et al., 2020; 2022; Toth, 2023). The weekly ReST group meetings will take place in easily accessible and non-challenging, city adjacent natural settings.

The Green Prescription intervention builds on an established nature-based mental health program – Häng med oss ut (approximately meaning "Go out with us") – developed by Therese Rosenkvist and adopted by the Swedish Outdoor Association (Friluftsfämjandet) who host the training of new instructors and oversee its implementation. Häng med oss ut group meetings will take place in the same settings as the ReST meetings.

The conventional mindfulness training intervention will build on the established Mindfulness-Based Stress Reduction (MBSR) program. The weekly MBSR group meetings will take place in indoor settings with minimal views and decorations, furnished only with the necessary arrangements for mindfulness practice.

The wait list condition will not involve any intervention activities over the five-week intervention period and the subsequent five-week follow-up period. The participants will not be specifically informed that other participants commence with interventions immediately but will get to choose which of the three active interventions (ReST, Conventional Mindfulness Training, Green Prescription) they want to join and receive a starting date 10+ weeks in the future.

Intervention Type
Behavioural

Primary outcome measure
Psychological distress is measured using the Depression Anxiety Stress Scales (Lovibond & Lovibond, 1995; also see Alfonsson et al., 2017) at baseline, 5 weeks (directly after the intervention), 10 weeks (1-month follow-up) and 26 weeks (6-month follow-up).

Secondary outcome measures
Each of the following outcomes will be measured at baseline, five weeks (directly after the intervention), 10 weeks (1-month follow-up) and 26 weeks (6-month follow-up):
1. Health-related quality of life measured using the Short Form Health Survey, 12-item (Jenkinson et al., 1997),
2. Psychological resilience measured using the State/Trait Assessment of Resilience (Lock et al, 2020) rating scale,
3. General cognitive functioning measured using the Cognitive Failures Questionnaire (Broadbent et al., 1982),
4. Trait mindfulness measured using the Five Facet Mindfulness Questionnaire (Bear et al, 2006),
5. Loneliness measured using the De Jong Gierveld Loneliness Scale (Lee et al., 2001),
6. Frequency and awareness of nature contact measured using the Intentional Nature Exposure Scales (Wood at al, 2019),
7. Trait nature connection measured using the Nature Connection Index, trait version (Richardson et al, 2019),
8. Concern for environmental threats measured using the Environmental Concerns Scale (Schultz et al., 2001),
9. Pro-environmental behavior measured using the Recurring Pro-environmental Behavior Scale (Brick, Sherman & Kim, 2017) and the pro-environmental behavior scale from the People & Nature Survey (2023),
10. Alignment of behavior with personal values measured using the Engaged Living Scale (Trompetter et al., 2013),
11. Healthcare service use measured using a bespoke set of questions covering the frequency of different healthcare visits, dose and frequency of any antidepressant or anxiolytic medication, number of sick days, and resources needed to access healthcare.
12. Before and directly after the interventions, we will also measure the acceptability of the interventions using prospective and retrospective versions, respectively, of the Theoretical Framework of Acceptability questionnaire (Sekhon et al., 2017).
13. In the 10 weeks (1-month follow-up) and 26 weeks (6-month follow-up) assessments, we will additionally measure continued use of health practices taught in the interventions with a bespoke question set.

The following processes will be measured in connection with the intervention activities. After each group meeting, we will measure:
14. Perceived restorative qualities in the environment measured using the Perceived Restorativeness Scale; Hartig et al., 1997a; 1997b)
15. State mindfulness measured using the State Mindfulness Scale (Tanay & Bernstein, 2013)

16. State nature connection measured using the Nature Connection Index, state version (Richardson et al, 2019)
17. Intervention group cohesion measured using the Intervention Group Environment Scale (Wilson et al., 2008)
18. Physical activity in the preceding week measured using the International Physical Activity Questionnaires (Booth, 2000)
19. Completed homework assignments in the preceding week measured using a bespoke question set

Overall study start date
04/11/2020

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Enrolled in university courses for at least 75% of full time during the study period
2. 18-40 years old
3. Motivated to participate in a health intervention
4. Able to plan for participating in accordance with the given schedule

Participant type(s)
Healthy volunteer, Patient, Learner/student

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Both

Target number of participants
260

Key exclusion criteria
1. Current severe mental health symptoms, suicidal ideation or self-harm
2. Current or previous psychotic or bipolar symptoms
3. Other health issues that could interfere with participation (e.g., moderate to severe allergies that can be triggered in nature visits)
4. Recent (<1 months) initiation or adjustment of regular medication that is expected impact psychological health
5. Previous participation in a nature- or mindfulness-based health intervention (minor unstructured engagement with nature activities, meditation, yoga, etc. are acceptable)

Date of first enrolment
17/04/2024

Date of final enrolment
12/09/2025

Locations

Countries of recruitment
Sweden

Study participating centre
Institute for Housing and Urban Research, Uppsala University
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Sponsor information

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Funder(s)

Funder type

Government

Funder Name
Horizon Europe Research and Innovation

Results and Publications

Publication and dissemination plan
We expect to publish two papers based on this study, in high-impact peer-reviewed journals for clinical studies and/or environmental psychology studies.

Intention to publish date
30/06/2027

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study will be stored in a publicly available repository (Swedish National Data Service; https://snd.se). The data will be made available there following a 2-year embargo period after final publication from the project, and remain available indefinitely. We will share data on all collected background characteristics and self-reports that can be shared without jeopardizing participant's anonymity. Where needed to protect participant's anonymity, data will be shared in aggregated or partially censored forms. Once data is made publicly available, no particular access criteria or restrictions will be applied. All participants will have consented to eventual sharing of their anonymized data as part of the enrollment process.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3		29/07/2024	No	No