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Can nature-based therapy with exercise and mindfulness boost biopsychosocial resilience in people with metabolic syndrome?

Submission date
10/06/2024

Recruitment status
No longer recruiting

Registration date
10/06/2024

Overall study status
Completed

Last Edited
10/06/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Metabolic Syndrome (MetS) is a group of conditions, including high blood sugar, high blood pressure, abnormal cholesterol levels, and obesity, that together increase the risk of developing type 2 diabetes, heart disease, stroke, and can lead to early death. In Austria, about 25% of the population is affected by MetS, highlighting the urgent need for accessible health programs to address this widespread lifestyle-related disease. Recently, there has been growing interest in nature-based therapies (NBTs), which involve activities like spending time in nature or exercising outdoors. These therapies have been shown to offer significant physical and mental health benefits, especially for people with sedentary lifestyles, MetS, and limited exposure to nature.

A clinical trial will test the effects of a nature-based intervention on people with MetS who don't spend much time in nature. The main goal is to see how these therapies can improve overall well-being and resilience to stress, measured by quality of life and allostatic load. This trial is part of a larger project called RESONATE, which includes similar studies in Salzburg, Austria (NATURE-MET-S), Padua, Italy (NATURE-MET-P), and Barcelona, Spain (NATURE-MET-B). Each study is conducted in different natural environments: coastal areas in Barcelona, urban green spaces in Padua, and rural mountainous regions in Salzburg. By comparing the effects of different natural settings on MetS, these studies aim to develop effective health programs that can help people with MetS lead healthier lives.

Who can participate?
A total of 140 MetS patients aged 40-65 years with an inactive lifestyle and little contact with nature will be recruited.

What does the study involve?
The study will last 6 months. After randomization into two groups (intervention group vs. control group), the intervention arm will be conducted in two consecutive rounds (fall 2024 and spring 2025). Participants in the control group will be assessed at the same time as the intervention group and will also have the opportunity to receive the nature-based therapy after the assessment period (180 days) (wait-list-control design). The 10-week nature-based

intervention consists of easy hikes and nature-based mindfulness training in the mountains of the city of Salzburg. The sustainability of the intervention will be monitored over a six-month period.

What are the possible benefits and risks of participating?
Potential benefits: The participants in the study have metabolic syndrome and are at increased risk of developing certain diseases, such as cardiovascular disease, due to the presence of metabolic syndrome and physical inactivity. Many scientific studies have shown that exercising in nature ("green exercise") is an effective activity for improving quality of life, well-being and reducing certain disease risks, such as cardiovascular disease. In addition, green exercise has additional positive psychophysiological effects compared to indoor exercise, which can benefit people with sedentary lifestyles, metabolic syndrome, and little contact with nature.
Participants in this study will have the opportunity to participate in a structured nature-based secondary prevention program free of charge. Potential benefits include improvements in health and subjective well-being. For the participants, completing this program could also be a first step towards a more active lifestyle in order to reduce certain risk factors for cardiovascular disease in the long term.

Potential risks:
Pain/inconvenience: Pain may occur during the blood draw. Measurement of lung function may be strenuous for participants. To minimize pain and inconvenience, all examinations will be performed by persons with appropriate professional qualifications and experience. Study participants will be informed verbally and in writing about the risk of pain.
Safety: During the intervention, participants will participate in hikes in nature. These hikes may cause shortness of breath or muscle aches. There is also a risk of falls, such as tripping over roots or slipping on unpaved trails. To ensure safety, all guided walks are led by trained therapists and qualified walking guides. They will inform study participants about the risks and how to minimize them, for example, by wearing appropriate equipment and footwear. All guides are also equipped with a first aid kit.
Tick-borne diseases: Throughout Austria, there is a risk of being bitten by ticks while outdoors. These can transmit diseases such as TBE (tick-borne encephalitis) or Lyme disease. Study participants will be informed of the risk of tick bites. They are advised to check their TBE vaccination status prior to the start of the intervention and to update if necessary. During outdoor sessions, each participant is advised to use tick repellent and wear closed clothing. Participants are also advised to check themselves for ticks after each session. If a tick has bitten, a physician must be called immediately to remove the tick and document the event. In this case, follow-up care must be provided for the next seven days.

From the researchers' perspective, the potential benefits to study participants outweigh the specific risks of the nature-based intervention.

Where is the study run from?
Paracelsus Medical University (Austria)

When is the study starting and how long is it expected to run for?
June 2023 to September 2025

Who is funding the study?
HORIZON EUROPE project RESONATE (https://resonate-horizon.eu/, project ID: 101081420)

Who is the main contact?
a.o. Univ. Prof. Dr. Arnulf Hartl, arnulf.hartl@pmu.ac.at
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Public, Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

Study information

Scientific Title
Nature-based therapy for Metabolic Syndrome - Salzburg

Acronym
NATURE-MET-S

Study objectives
A nature-based therapy comprising green exercise and mindfulness training enhances biopsychosocial resilience in individuals with metabolic syndrome.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/06/2024, Ethics board of the Paracelsus Medical University Salzburg (Strubergasse 21, Salzburg, 5020, Austria; +43 662 2420-80356; ethik.kommission@pmu.ac.at), ref: PMU-EK-2024-0001

Study design
Single-center interventional non-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Secondary prevention for individuals aged 40-65 years with metabolic syndrome (MetS)

Interventions
The present single-centered randomized controlled trial evaluates the effect of a nature-based therapy on the biopsychosocial resilience of individuals with metabolic syndrome.

A total of 140 participants will be recruited and randomly assigned to either the intervention or control group. The intervention will be conducted in two consecutive rounds, the first in September 2024 and the second in March 2025. The control group participants will undergo examination simultaneously with the intervention group. Subsequently, they will have the opportunity to participate in the nature-based therapy program (waiting-list control design).

The intervention group (n=70) will receive the following treatment: The intervention is a nature-based therapy (NbT) program comprising two components: green exercise and nature-based mindfulness training. Green exercise is conducted as hikes on the Salzburg city mountains. Each hike is approximately 1.5 to 2 hours in duration (3-6 km, 100-300 height meters). A heart rate monitor (wristwatch) will be provided to each participant, which will be calibrated to their specific gender, age, height, and weight. The aforementioned monitor will be utilized

throughout the entirety of the intervention. It is recommended that participants complete the hikes within the range of 60-70% of their maximum heart rate. During the hiking sessions, participants will engage in 20 minutes of mindfulness training based on concentrative movement therapy (Stolze & Badura-MacLean, 2002), a body psychotherapy method that combines physical movements and concentration to promote awareness and mindfulness of one's own body.

The intervention is scheduled to last for a total of 10 weeks. It is recommended that the NBT be conducted on three occasions per week. In the initial week, all participants are required to engage in 3 guided hikes, which will be conducted by both a hiking guide and a mindfulness trainer/psychotherapist. The number of participants per group is limited to a maximum of 15 individuals. The objective of the intervention is to teach exercise and mindfulness training to participants so that they may continue to practice it independently. In weeks two through five, participants may elect to embark on the hikes independently or to participate in the guided hikes (3 x per week). In weeks 6-10, no further guided hikes will be offered; participants will be encouraged to conduct the sessions independently (3x per week). Each therapy sessions is documented by the participants themselves using the smartphone application MyCap.

The control group will not receive any intervention during the assessment period. Nevertheless, they will be offered the NBT after the data assessment period (waiting list control design).

Data is assessed for the intervention and control group on day 1, day 35, day 70 and day 180 (last follow-up).

The randomization process will be conducted using an open-source add-in for Microsoft Excel (Kraus, 2014). Age and gender will be used as stratification factors. The Kullback-Leibler divergence method will be employed as the allocation method (Endo et al., 2006). The randomization and stratification processes will be conducted by a biometrician who is not directly involved in the recruitment of study participants.

Intervention Type
Mixed

Primary outcome(s)
1. Biopsychosocial resilience is measured using:
1.1. Quality of Life (measured using SF-12), and
1.2. Allostatic Load Index (ALI) using following AL parameters: ALI I: DHEA-S, HRV, SBP, DBP, RHR, PEF, HDL Cholesterol, LDL Cholesterol, Triglycerides, HbA1C, Waist-hip ratio, CRP, IL-6, TNF-alpha; ALI II: DHEA-S (saliva), HRV, SBP, DBP, RHR, PEF, Waist-hip ratio, CRP (saliva)) at day 1, day 35 and day 70.
2. Perception of the intervention (affect) and short-term effects are measured via MyCap mobile app at the individual therapy sessions (3 x per week over 10 weeks): Nature Connection (INS), Individual or group setting, transportation used, Affective states (SPANE, PRS), ecological aspects, satisfaction

Key secondary outcome(s))
1. Vital parameter and lung function parameters at day 1, day, 35, day 70
1.1. Height, weight, oxygen saturation
1.2. Forced expiratory spirometry (PEF, FEV1, FVC, MEF)
2. Laboratory parameters at day 1, day, 35, day 70
2.1. Full blood analysis (blood sampling from the vein)

3. Resilience, measured using the questionnaires State-Trait-Assessment of Resilience Scale (STARS), Perceived Stress Scale (PSR) and Brief Sense of Coherence Scale (SOC-3) at day 1, day, 35, day 70, day 180
4. Mindfulness, measured using the questionnaire Five Facet Mindfulness Questionnaire (FFMQ-15) at day 1, day, 35, day 70, day 180
5. Physical activity, measured using the questionnaire International Physical Activity Questionnaire – Short Form (IPAQ-SF) at day 1, day, 35, day 70, day 180
6. Nature contact, measured using the questionnaires Inclusion of Nature in Self Scale (INS), Nature Connectedness Index (NCI), Direct & Indirect Nature Contact at day 1, day, 35, day 70, day 180
7. Subjective well-being and quality of life, measured using the questionnaires Intercultural Quality of Life Comic (iQOLC) and OECD-4 at day 1, day, 35, day 70, day 180
8. Loneliness, measured using the questionnaire the De Jong Gierveld Loneliness Scale at day 1, day, 35, day 70, day 180
9. Community cohesion, measured using the questionnaire Community Cohesion Scale at day 1, day, 35, day 70, day 180
10. Motivation, using the questionnaire Ideal self, and self-determined motivation

Furthermore, the following integrative evaluation parameters will be assessed:
1. Environmental aspects, measured using the questionnaires Perception of local nature (PANS-6), Environmental concerns, Revised Pro-Environmental Behavior Scale (R-PEBS) at day 1, day, 35, day 70, day 180
2. Health economic aspects:
2.1. QUALYs (calculation from SF-12)
2.2. Use of Care Services (day 70, day 180)
2.3. Willingness to pay via contingent valuation method (CVM) at day 70
3. Process evaluation, measured via questionnaires assessing the satisfaction with the intervention, willingness to repeat and willingness to recommend at day 35 and day70
4. In addition, qualitative interviews are conducted with study participants and members of the study team for process evaluation after the intervention starting at day 70.

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Individuals aged between 40 and 65 of any gender
2. Individuals diagnosed with metabolic syndrome according to the NCEP ATP III criteria (NCEP, 2001)
3. Sedentary lifestyle: Category 1 (low physical activity) of the International Physical Activity Questionnaire – Short Form (IPAQ-SF))
4. Low nature users: Category 1, 2 und 3 of the Monitor of Engagement with the Natural Environment Survey (MENE) – question “nature use” (Natural England, 2020)
5. Smartphone users

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Acute contraindications:
1.1. Malignant hypertension
2. Contraindications or differential diagnosis
2.1. Severe respiratory or lung disease (COPD according to GOLD Standard 3 and 4, severe asthma, emphysema)
2.2. Arteriosclerotic event (e.g. myocardial infarction) < 6 months ago
2.3. Uncontrolled metabolic diseases (e.g. uncontrolled diabetes mellitus)
2.4. insulin-dependent diabetes mellitus
2.5. Diagnosis or treatment of a malignant tumors < 3 years in the past
2.6. Orthopedic illnesses that do not allow participation in hikes
3. Factors that prevent or hinder participation in the intervention program
3.1. Alcohol abuse
3.2. Pregnancy
3.3. insufficient knowledge of German language (written and spoken)
4. Factors that prevent self-management:
4.1. Presence or indication of clinical depression (< 13 points WHO-5)
4.2. Serious other untreated psychiatric illnesses (e.g. schizophrenia)
5. Certain medication intake:
5.1. Taking preparations for weight reduction
6. Participation in another interventional study within the period of the clinical trial (t1-t4) and less than 4 weeks before the start of the trial (t1)
7. Participation in therapeutic weight loss programs within the period of the clinical study (t1-t4) and less than 8 weeks before the start of the study (t1)

Date of first enrolment
18/06/2024

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
Austria

Study participating centre
Paracelsus Medical University Salzburg, Institute of Ecomedicine
Strubergasse 22
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Study participating centre
Salzburg University Hospital, University Clinic for Internal Medicine I
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Sponsor information

Organisation
Paracelsus Medical University

ROR
https://ror.org/03z3mg085

Funder(s)

Funder type
Government

Funder Name
European Union's Horizons Europe research and innovation programme under grant agreement No. 101081420

Results and Publications

Individual participant data (IPD) sharing plan
1. The datasets generated during and/or analyzed during the current study will be stored in a publicly available repository.
As the primary repository, we will share and archive data on the Open Science Framework (https://osf.io/), which is a free and accessible platform. All users registered on the OSF platform will have access to the data.
To enhance discoverability and facilitate the integration of our findings within the broader

nature-based solutions community, we will disseminate information and provide links to our results and datasets on OPPLA (https://oppla.eu/), the EU repository for nature-based solutions. OPPLA is an open platform that can be accessed by individuals for a variety of purposes, including by those with no scientific background. This will ensure that the results of the study will also be accessible to healthcare professionals, therapists, and municipalities.
Type of data: Aggregated quantitative data of primary and secondary outcomes (e.g. sum scores of SF-12, sum scores of indices). The data will be made available after the publication of results in peer-reviewed journals. Consent from participants to share the data will be obtained. Each study participant will be assigned a six-digit identification number (ID) for anonymization purposes. Personal data will only be stored in ID-encrypted form. The password-protected master list, which contains the assignment of IDs to personal data, ensures that personal data can be deleted when the study is completed. The master list is stored on a secure data server at the Paracelsus Medical University of Salzburg and is only accessible to the researcher responsible for recruitment, eligibility checks and allocation. The master list, which combines the ID and name, is deleted prior to the publication of the study data.
2. Datasets generated during and/or analyzed during the current study will also be available upon request from a.o. Univ. Prof. Dr Arnulf Hartl, Paracelsus Medical University Salzburg, Institute of Ecomedicine, Strubergasse 22, 5020 Salzburg, Austria, arnulf.hartl@pmu.ac.at
Type of data: Aggregated quantitative data of primary and secondary outcomes (e.g. sum scores of SF-12, sum scores of indices). The data will be made available after the publication of results in peer-reviewed journals. Consent from participants to share the data will be obtained. Each study participant will be assigned a six-digit identification number (ID) for anonymization purposes. Personal data will only be stored in ID-encrypted form. The password-protected master list, which contains the assignment of IDs to personal data, ensures that personal data can be deleted when the study is completed. The master list is stored on a secure data server at the Paracelsus Medical University of Salzburg and is only accessible to the researcher responsible for recruitment, eligibility checks and allocation. The master list, which combines the ID and name, is deleted prior to the publication of the study data.
4. The datasets generated and/or analyzed during the current study will be published as a supplement to the results publication, should this be deemed appropriate by the relevant journal.

IPD sharing plan summary

Stored in publicly available repository, Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	05/02/2024	10/06/2024	No	Yes
Protocol file	version 4	27/05/2024	10/06/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes