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Enhancing well-being and resilience through nature-based mindfulness activities. The case study of Padua with people at risk of metabolic disorder (NATURE-MET-P)

Submission date
22/07/2024

Recruitment status
Recruiting

Registration date
09/09/2024

Overall study status
Ongoing

Last Edited
25/07/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English Summary
Background and study aims
Metabolic Syndrome (MetS) is a cluster of conditions, including high blood sugar, high blood pressure, abnormal cholesterol levels, and obesity, that collectively increase the risk of developing type 2 diabetes, heart disease, stroke, and can lead to premature death. In Europe, about 25% of the population is affected by MetS. Recently, there has been a growing interest in nature-based therapies (NBTs), which involve activities such as spending time in nature or exercising outdoors. These therapies have demonstrated significant physical and mental health benefits, particularly for individuals with sedentary lifestyles, MetS, and limited exposure to nature. For that reason, the aim of the study is to investigate the positive effects of nature-based therapies in sedentary individuals at risk of metabolic syndrome and see how these therapies can improve overall well-being and resilience to stress. This trial is part of a larger project called RESONATE, which includes similar studies in Padua, Italy (NATURE-MET-P) Salzburg, Austria (NATURE-MET-S), 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 at risk of MetS lead healthier lives.

Who can participate?
People at risk of metabolic syndrome aged 40-65 years with an inactive lifestyle and little contact with nature

What does the study involve?
The study will last 5 weeks with an additional assessment after another 5 weeks. After random allocation into two groups (intervention group vs control group), the intervention group 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 (wait-list-control

design). The 5-week nature-based intervention consists of 60 minutes of walking and mindfulness relaxation activities with a total of 15 sessions for each participant (3 times a week for 5 weeks).

What are the possible benefits and risks of participating?
The participants in the study at risk of metabolic syndrome are at increased risk of developing certain conditions, due to the presence of physical inactivity, poor quality of life and stressful routines. 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 risk conditions, such as cardiovascular disease. In addition, green exercise has other positive psychophysiological effects compared to indoor exercise, which can benefit people with sedentary lifestyles, at risk of 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 and better quality of life in the long term.
During the intervention, there would be a risk of falls, such as tripping over roots or slipping on unpaved trails. For this reason, participants will be guided during the first few weeks of sessions. Additionally, during the self-guided sessions, some study collaborators will remain around the urban parks to ensure that all participants are safe.
Air quality: According to data from ARPA Veneto (https://www.arpa.veneto.it/), the city of Padua exceeds the permitted levels of PM10 and PM2.5 on some days. For this reason, the informed consent states that any participant concerned about their health may skip sessions on days with high pollution levels.
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?
University of Padua (Italy)

When is the study starting and how long is it expected to run for?
June 2023 to September 2026

Who is funding the study?
HORIZON EUROPE project RESONATE

Who is the main contact?
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3. Monica Bolognesi, monica.bolognesi@studenti.unipd.it

Study website
https://resonate-horizon.eu

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
101081420

Study information

Scientific Title
Randomised controlled trial examining the efficacy of an urban nature-based therapy for increased biopsychosocial resilience amongst sedentary individuals at risk of metabolic syndrome

Acronym
RESONATE

Study hypothesis

Current evidence suggests that NbTs can have a beneficial impact on mental health and wellbeing (Britton et al., 2020; Nguyen et al., 2022; Richardson et al., 2021). However, high-quality evidence, based on well-controlled trials, is lacking and the biopsychosocial mechanisms are again insufficiently understood (White et al., 2023).

Furthermore, heterogeneity in terms of intervention protocols and outcomes between studies makes it difficult to synthesise and compare causal evidence on the efficacy of NbTs (Hartig et al., 2014; Annerstedt & Währborg, 2011).

Using comparable high-quality Randomised Controlled Trial (RCT) designs, the study will provide essential knowledge regarding the efficiency of NbTs in a high-risk population group at risk of Metabolic Syndrome (MtS). The rationale behind choosing a population at risk of MtS is that this is a group of individuals with a high risk of developing various non-communicable diseases (NCDs), such as coronary heart disease and stroke (Mohamed et al., 2023), and are likely to benefit from improved biopsychosocial resilience. MtS is characterised by a cluster of conditions that occur together, such as being overweight and having high blood pressure, and blood glucose levels (Hayden, 2023). All the parameters may hypothetically be reduced and improved by NbT, which means better mental and physical health and stress reduction (Patwary et al., 2024). The results are expected to be beneficial for the implementation of nature-based interventions as a preventive approach in a high-risk population, with significant health gains.

According to these premises, the primary objective of the clinical study is to analyse the impact of a series of short, initially staff-guided, and then self-directed mindful immersions in nature, on biopsychosocial resilience in a sedentary population at risk of MtS and low nature use prior to the study.

It is hypothesized that the nature intervention (mindfulness and light walking) could:
1. Reduce psychophysical stress in participants: decrease pro-inflammatory parameters (saliva), heart rate, blood pressure, and waist-to-hip ratio and increase respiratory flow.
2. Have a positive effect on general health (physical activity, mental health) and well-being (subjective well-being, emotions, loneliness, environmental attitudes, local nature attitudes, pro-environmental behaviours, psychological resilience, motivation, acceptability)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/02/2024, Comitato Etico Della Ricerca Psicologica (area 17) (Via Venezia 8, Padova, 35131, Italy; +39 (0)498276600; comitato.etico.area17@unipd.it), ref: 458-a

Study design
Single-center interventional trial using a two-arm wait-list design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Built environment/local authority, Laboratory, Other

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

Participant information sheet

Condition
Psychophysiological parameters in participants at risk of metabolic syndrome

Interventions
A total of 140 participants will be recruited and randomly assigned to either the intervention or control group, balancing for gender and age. Participants from both the control and intervention groups will be assigned to one of two rounds planned in the study starting in September 2024 and March 2025, respectively. 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 a treatment consisting of a nature-based therapy (NbT) program with two components: outdoor activities and nature-based mindfulness training. The outdoor activities will take place in the main urban parks of the city of Padua. The intervention will consist of 15 sessions (5 weeks, 3 times per week) of roughly 60 minutes, 10 each, divided into 10 minutes of light walking, 10 minutes of relaxation/mindfulness, 10 minutes of walking, 10 minutes of relaxation/mindfulness, 10 minutes of walking and 10 minutes of "diary reflection". Each therapy session will be evaluated on quality of therapy, pleasantness of the site etc, by each participant through the MyCap application. 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). The assessment phase is planned on day 0, day 35, and day 70.

Intervention Type
Mixed

Primary outcome measure
1. Biopsychosocial resilience is measured using these measures on day 0, day 35 and day 70:
1.1. Quality of Life measured using SF-12
1.2. Allostatic Load Index (ALI) measured using the following parameters:
1.2.1. Heart Rate Variability (HRV)
1.2.2. Systolic Blood Pressure (SBP)
1.2.3. Diastolic Blood Pressure (DBP)
1.2.4. Resting Heart Rate (RHR)
1.2.5. Peak Expiratory Flow (PEF)
1.2.6. Waist-hip ratio
1.2.7. C-Reactive Protein (CRP) (saliva)
2. Perception of the intervention (affect) and short-term effects are measured via the MyCap mobile app at the individual therapy sessions (3 x per week over 5 weeks):
2.1. Nature connectedness measured using Inclusion of Nature with Self (INS)
2.2. Transportation used measured using ad hoc question
2.3. Affective states:
2.3.1. Emotions measured using the Scale of Positive and Negative Experience (SPANE)
2.3.2. Perceived restorativeness measured using the Perceived Restorativeness Scale (PRS)
2.4. Ecological aspects measured using ad hoc questions
2.5. Satisfaction measured using ad hoc questions

Secondary outcome measures
Measured on day 0, day 35 and day 70 (unless indicated):
1. Sociodemographic information collected using ad hoc questions (day 0 only)
2. Trait mindfulness measured using the Five Facet Mindfulness Questionnaire (FFMQ-15)
3. Environmental habits and childhood experiences (only day 0) from PANS-M1Q1 - People & Nature Survey, 2021
4. Current indirect contact with nature from PANS-M1Q1 - People & Nature Survey, 2021
5. Physical activity measured using the International Physical Activity Questionnaire Short Form (IPAQ-SF)
6. Subjective well-being measured using the Organisation for Economic Co-operation and Development Survey (OECD-4)
7. Well-being, emotions measured using the Scale of Positive and Negative Experience (SPANE)
8. Loneliness measured using the De Jong Gierveld Loneliness Scale
9. Environmental concern measured using the Environmental Concern Scale
10. Local nature attitudes measured using the People & Nature Survey (PANS-6)
11. Pro-environmental behaviors measured using Pro-environmental Behaviors Scale (RPEBS)
12. Resilience measured using the State-Trait Assessment of Resilience Scale (STARS)
13. Perceived restorativeness measured using Perceived Restorativeness Scale (PRS)
14. Motivation (self-determined motivation) measured using Ideal Self, ad hoc scale
15. Acceptability measured using Sekhon et al, 2018 scale
16. Nature connectedness measured using the Nature Connectedness Index (NCI)
17. Sense of community measured using the Brief Sense of Community Scale
18. Social desirability measured using the Marlowe-Crowne Social Desirability Scale (MC-SDS)
19. Contingent evaluation (willingness to pay) measured using an ad hoc scale (only at day 70)
20. Use of care services (cost savings) measured using an ad hoc scale

Moreover, at day 180 the following integrative evaluation parameters will be assessed:
1. Use of care services (cost savings) measured using an ad hoc scale
2. Overall satisfaction with the program measured using an ad hoc scale

Overall study start date
01/06/2023

Overall study end date
02/09/2026

Eligibility

Participant inclusion criteria
1. People at risk of metabolic syndrome (at least three of five of the following criteria):
1.1. Abdominal obesity: Waist circumference >102 cm (men), >88 cm (women)
1.2. Triglycerides: ≥150 mg/dL or Rx
1.3. HDL cholesterol: <40 mg/dL (men), <50 mg/dL (women) or Rx
1.4. Blood pressure: ≥130/≥85 mmHg or Rx
1.5. Fasting glucose: ≥110mg/dL or Rx
2. 40-65 years old
3. Sedentary behavior [Category 1 (Low) or 2 (Moderate) of IPAQ-SF]
4. Ability to participate in tours in urban green areas
5. Low nature contact (probably <30 min/week actively engaged)

Participant type(s)
Employee, Resident, Population

Age group
Adult

Lower age limit
40 Days

Upper age limit
65 Days

Sex
Both

Target number of participants
140

Participant exclusion criteria
1. Active lifestyle (Category 3 [High] of IPAQ-SF)
2. Pregnancy
3. Enrollment in any other interventional clinical trial
4. Acute depression

Recruitment start date
01/03/2024

Recruitment end date
01/06/2025

Locations

Countries of recruitment
Italy

Study participating centre
University of Padua
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Sponsor information

Organisation

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Sponsor type
University/education

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ROR
https://ror.org/00240q980

Funder(s)

Funder type
Government

Funder Name
Horizon Europe

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journals

Intention to publish date
02/09/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available on request from Prof. Angelica Moè (angelica.moe@unipd.it).
The type of data that will be shared: All data collected via the MyCap app that are anonymized
Dates of availability: After the end of data collection
Whether consent from participants was required and obtained: Each participant will need to sign the informed consent form, which outlines all measurements, timelines, and risks.
Comments on data anonymization: The data may be disclosed to University of Padua staff and collaborators, including independent contractors, who provide support for the implementation and management of activities envisaged by the research project. The collected data will be used

(disseminated or communicated) exclusively in an aggregated and anonymous manner for scientific publication purposes. As a rule, the collected data are not transferred to countries outside the European Union. In any case, the University ensures compliance with security regulations for the protection of the personal data of the individuals concerned.

IPD sharing plan summary

Available on request