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GreenME Nature-based therapy evaluation, Parc Sanitari Sant Joan de Déu

Submission date
27/03/2025

Recruitment status
Recruiting

Registration date
16/05/2025

Overall study status
Ongoing

Last Edited
16/05/2025

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
The increasing prevalence of mental health disorders, such as anxiety and depression, has become a significant global health concern (WHO, 2022). Traditional mental health treatments, while effective, often come with limitations, including high costs, side effects, and limited accessibility (WHO, 2021; The Lancet Global Health, 2020). Meanwhile, spending time in nature has been shown to reduce stress, improve mood, and enhance cognitive function (Yang et al, 2021; Yang et al, 2023; Triguero-Mas et al, 2017), among other health benefits. Therapeutic interventions in nature (which we call here “nature-based therapies”, or NBT), led by trained professionals can further enhance these benefits (Busk et al, 2022). Professional guidance can help individuals develop coping strategies, build resilience, and foster a deeper connection with nature (Sempik & Bragg, 2016). But, these types of therapies face some challenges such as cost and lacking support from the medical community.

This study aims to improve the scientific evidence on whether and how NBTs work for improving mental health and wellbeing and for whether they are relatively low cost compared to other types of treatments. Focusing on people who experience significant stress in their daily life, this study aims to explore if nature-based therapies are more effective than other types of treatment in improving participant’s mental health. This study will also evaluate whether NBTs can be a less expensive way to treat mental health conditions.

Who can participate?
Anyone can participate in this study if they meet the following criteria:
• Between the ages of 18 – 75 years
• Are willing and able to participate in the forest bathing program
• Stress interferes with their daily life (as assessed by the screening questionnaire)
• Either: 1) frequently experiences of discrimination or prejudices in daily life OR 2) experiences poor sleep quality/poor mood/low energy levels/sadness/fatigue/anxiety (as assessed by the screening questionnaire)
• They have not participated in a similar nature-based therapy program in the past month

What does the study involve?
Participating in the study involves: 1) Completing a set of questionnaires about your health, well-

being, experiences and personal characteristics before the study starts. 2) participating in a 12-week forest therapy program twice a week for 120 minutes (2 hours) each session or a grief therapy program meeting every week for 90 minutes for 12 weeks. You would be randomly assigned to participate in either the forest therapy or the alternative program (note: those not receiving the forest therapy program would still be able to participate in this program later, after the study is over) And 2) completing questionnaires about your experiences during the study, and your health and well-being just after the program ends and again 1 month after the program ends and finally 3 months after the program ends.

What are the possible risks and benefits of participating?
The benefits of participating include that your participation may help contribute to future knowledge about the benefits of nature-based therapies. Other people in the future may benefit from improved or more availability of nature-based therapies due to your participation. In addition, you may benefit from the nature-based therapy itself or from the alternative program that you participate in as part of the study.

We do not foresee any serious risks from participating in the study. However, it is possible that you experience physical discomfort (although we have tried to make the program accessible to everyone regardless of physical abilities). You may also feel uncomfortable answering sensitive questions on the questionnaires. You are not required to answer any questions if you do not want to.

Where is the study run from?
The study is run from the Fundació Sant Joan de Déu - Parc Sanitari Sant Joan de Déu, Xarxa de Salut Mental.

When is the study starting and how long is it expected to run for?
The study will start in April 2025. Each participant will be in the study for approximately 4 months, including participating in the questionnaires and the 12-week intervention. Enrollment for the study will end by July 2026.

Who is funding the study?
The funding for the study comes from Horizon Europe.

Who is the main contact?
The main contact is Dr Margarita-Triguero Mas, mtrigueroma@uoc.edu

Study website
https://greenme-project.eu/

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Horizon Europe Grant Agreement 101084198

Study information

Scientific Title
Advancing Greencare in Europe: an integrated multi-scalar approach for the expansion of nature-based therapies to improve Mental health Equity (GreenME). Nature-based therapy evaluation, PSStJoanDéu.

Acronym
GreenME-PSSJD

Study objectives
Primary:
Nature-based therapies tested in GreenME are superior to Usual Care in decreasing participants' perceived stress when comparing baseline to just after exposure measurement.

Secondary:
1. Nature-based therapies tested in GreenME are superior to Usual Care in improving participants' quality of life when comparing baseline to just after exposure measurement.
2. Nature-based therapies tested in GreenME are a cost-effective intervention compared to Usual Care in terms of quality-adjusted life years (QALYs), healthcare, and societal costs.
3. Nature-based therapies tested in GreenME are superior to Usual Care in improving participants' subjective wellbeing when comparing baseline to just after exposure measurement.
4. Nature-based therapies tested in GreenME are superior to Usual Care in reducing perceived stigmatisation when comparing baseline to just after exposure measurement.
5. Changes to different mental health indicators (perceived stress, quality of life, subjective wellbeing) are maintained over time (1 month, 3 months after exposure ended) for participants that continue exposure to the nature-based therapies tested in GreenME and participants that leave exposure to GreenME tested nature-based therapies after GreenME evaluation.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 19/12/2024, Research Ethics Committee of the Universitat Oberta de Catalunya (Rambla de Poblenou, 154, Barcelona, 08018, Spain; +34 934505200; comite_etica@uoc.edu), ref: CE24-PR55

2. Not yet submitted 27/03/2025, CEIm de la Fundació Sant Joan de Déu (Edifici Docent Sant Joan de Déu, C/ Santa Rosa, 6, 1a planta, Esplugues de Llobregat, 08950, Spain; -; frecerca.ceic@sjd.es), ref: none

Study design
Interventional non-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Hospital, Other

Study type(s)
Quality of life, Treatment

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

Health condition(s) or problem(s) studied
Treatment of high stress

Interventions
1. Intervention: This intervention is designed as a recovery-based intervention. It involves direct engagement with nature, specifically forest environments, through activities tailored to participants' needs and preferences. These activities are not formal psychological therapy, but rather therapeutic and health-promoting experiences, as they focus on engaging with nature in a supportive environment facilitated by a guide. It focuses on nature-based activities that promote stress reduction and overall well-being, offering participants valuable tools for managing the challenges they face. The activities within the intervention will be personalized based on each individual's specific needs and challenges. It is important to note that all activities and sharing in the circle are entirely voluntary; while the guide encourages participation, none of the activities is ever mandatory.
• Each session will begin with an introductory activity to foster initial contact among participants
• Followed by a slow-paced walk. During the walk, the guide may suggest activities involving interpersonal interaction or individual exercises. Several stops will be made along the route, during which the guide will offer activities aimed at enhancing proprioception, and engaging the senses of hearing, touch, sight, smell, and taste.

• After completing these sensory activities, the group will engage in a voluntary sharing circle where participants can reflect on and share their experiences.
• The session will continue with activities designed to connect participants to nature through mirror neuron exercises and direct exposure, followed by additional sharing circles.
• At the conclusion of the session, after a final immersive experience, the guide will lead a brief closing reflection and a shared moment of gratitude.

2. Usual Care: : The “waitlist” participants will participate in a grief therapy group. These therapy groups are slow opening in nature, meaning their composition will evolve as members exit the group either upon completing the therapeutic process (discharge) or due to abandonment. Participants are assigned to groups based on their relationship to the deceased (e.g., loss of a spouse, parent, child, sibling, etc.), in order to foster some degree of homogeneity. However, all groups currently exhibit a level of heterogeneity among participants. This diversity is also reflected in the varying stages of the grieving process that group members are experiencing upon joining. The duration of participation is flexible and is determined by the individual's progress, in consultation with the clinician. The content of the sessions is not standardized across groups, meaning each group’s focus may differ week to week. There is also variability in the sessions led by the four professionals involved. Each therapist tailors their approach to meet the specific needs of their group. The overarching goal of the sessions is to provide participants with strategies and tools to effectively process their grief, ultimately facilitating an appropriate and personalized grief recovery process.
• Weekly sessions, lasting 90 minutes (i.e. shorter duration than the NBT).
• Group sizes ranging from 10 to 12 participants.

A randomization sequence will be computer-generated by a researcher from the Core Research Team not involved with participant recruitment and data collection. This researcher will then print out the sequence, printing one element (intervention or waitlist) of the sequence on a separate page and putting each page in separate envelopes, which will be marked with serial numbers. Each sequential envelope will be opened as participants enrol to determine their group.

Intervention Type
Behavioural

Primary outcome measure
1. Perceived stress is measured using the Perceived Stress Scale 10 items (PSS-10) at Screening /Baseline, 10 weeks, 14 weeks, and 22 weeks for the intervention group and at Screening /Baseline, 10 weeks, 20 weeks, and 24 weeks for the waitlist group
2. Quality of life is measured using EuroQol 5 Dimensions 5 levels (EQ-5D-5L) at Screening /Baseline, 10 weeks, 14 weeks, and 22 weeks for the intervention group and at Screening /Baseline, 10 weeks, 20 weeks, and 24 weeks for the waitlist group
3. Wellbeing is measured using ONS-4 at Screening/Baseline, 10 weeks, 14 weeks, and 22 weeks for the intervention group and at Screening/Baseline, 10 weeks, 20 weeks, and 24 weeks for the waitlist group

Secondary outcome measures
1. Anxiety is measured using Generalized Anxiety Disorder-7 (GAD-7) at Screening/Baseline, 10 weeks, 14 weeks, and 22 weeks for the intervention group and at Screening/Baseline, 10 weeks, 20 weeks, and 24 weeks for the waitlist group
2. Sleep quality is measured using PSQI-2 at Screening/Baseline, 10 weeks, 14 weeks, and 22 weeks for the intervention group and at Screening/Baseline, 10 weeks, 20 weeks, and 24 weeks

for the waitlist group
3. Emotional regulation is measured using Difficulties in Emotion Regulation Scale (DERS-16) at Screening/Baseline, 10 weeks, 14 weeks, and 22 weeks for the intervention group and at Screening/Baseline, 10 weeks, 20 weeks, and 24 weeks for the waitlist group
4. Self-esteem is measured using Rosenberg Self-esteem Questionnaire (RSES) at Screening /Baseline, 10 weeks, 14 weeks, and 22 weeks for the intervention group and at Screening /Baseline, 10 weeks, 20 weeks, and 24 weeks for the waitlist group
5. Depression is measured using Patient Health Questionnaire-9 (PHQ-9) at Screening/Baseline, 10 weeks, 14 weeks, and 22 weeks for the intervention group and at Screening/Baseline, 10 weeks, 20 weeks, and 24 weeks for the waitlist group

Overall study start date
01/09/2023

Completion date
31/08/2027

Eligibility

Key inclusion criteria
1. Between the ages of 18 – 75 years
2. Comply with eligibility criteria to access and take part in the evaluated intervention
3. Stress interference in daily life being significantly or very significantly (as assessed by the screening questionnaire)
4. Either: often or very often experiences of discrimination or prejudices in daily life OR Yes-experiencing persistent poor sleep quality/poor mood/low energy levels/sadness/fatigue /anxiety (as assessed by the screening questionnaire)
5. No previous (last year) or current participation in the same type of nature-based therapy we are evaluating

Participant type(s)
Patient, Population, Service user

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
78

Key exclusion criteria

1. Intellectual disability (ICD-11 6A00)
2. Phobias that can highly impact the capacity to benefit from our evaluated interventions, such as social and insect-related phobias (ICD-11 6B02, 6B03, 6B04)
3. Dissociative behaviors (ICD-11 6B60, 6B61, 6B62, 6B63, 6B64, 6B65, 6B66, 6E65, 6B6Y, 6B6Z)
4. Mental or behavioral symptoms, signs or clinical findings that can highly impact the capacity of the intervention group to benefit from our evaluated interventions or that increases their potential to become difficult cases to handle by guides (ICD-11 MB23.0, MB23.R, MB23.S)

Date of first enrolment
15/04/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
Spain

Study participating centre
Fundació Sant Joan de Déu - Parc Sanitari Sant Joan de Déu, Xarxa de Salut Mental
Carrer Pablo Picasso, 12
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Sponsor information

Organisation
Universitat Autònoma de Barcelona

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Sponsor type
University/education

Website
https://www.uab.cat

ROR
https://ror.org/052g8jq94

Funder(s)

Funder type
Government

Funder Name
HORIZON EUROPE Framework Programme

Alternative Name(s)
Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The main results of this study will be published in an academic journal, along with the results of the other centers participating in the larger study. The results of the study will also be avaialble via the project website. The results will also help inform guideliens for scaling up nature-based therapies and other types of green care being developed by the consortium working on the GreenME study .

Intention to publish date
01/05/2027

Individual participant data (IPD) sharing plan
The anonymized version of the datasets generated during this study will be stored in a publicly available repository (not yet identified), and can be found through information which will be posted on the project website.

IPD sharing plan summary
Stored in publicly available repository