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GreenME Nature-based therapy evaluation, case 2 (Consorci Sanitari Maresme)

Submission date	Recruitment status	[ ] Prospectively registered
13/03/2025	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/05/2025	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/05/2025	Mental and Behavioural Disorders	[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?

• Between the ages of 18 – 75 years
• Are willing and able to participate in the therapeutic horticulture 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 6-

week therapteutic horticulture program twice a week for 90 minutes each session or a different program lasting the same among of time. You would be randomly assigned to participate in either the therapeutic horticulture or the alternative program (note: those not receiving the therapeutic horticulture 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 Day Centre of Hospital Mataró (Spain)

When is the study starting and how long is it expected to run for?
September 2023 to August 2027

Who is funding the study?
Horizon Europe

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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. Case 2 (Consorci Sanitari Maresme)

Acronym
GreenME

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. submitted 05/02/2025, CEI Consorci Sanitari del Maresme (Hospital Mataró, Carr. de Cirera, 230, Mataró, 08304, Spain; +34 93 741 77 00; assajosclinics@csdm.cat), ref: Codi CEIm 11/25

2. approved 23/01/2025, Research Ethics Committee of the Universitat Oberta de Catalunya (Rambla de Poblenou, 154, Barcelona, 08018, Spain; +34 934505200; comite_etica@uoc.edu), ref: CE24-PR59

Study design
Interventional non-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life, Treatment

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

Interventions
1. Intervention (therapeutic horticulture): This intervention is designed as a recovery-oriented activity that – through therapeutic, health-promoting activities- fosters direct contact with nature. It is important to note that this intervention does not include formal psychological therapy. The specific activities will be tailored to each participant's individual needs and preferences, ensuring a personalized approach that effectively addresses their specific challenges. Each participant will receive two sessions per week over consecutive 6 weeks with a total of twelve sessions. Each session will last 90 minutes. Only low-to-middle physical activities will be allowed during the exposure sessions.

2. Usual Care: : The "waitlist" group will have the option to participate in one of two activities that are based on structured physical exercise activities, designed to support recovery through movement, social interaction, and stress reduction, while also combating sedentary behaviour: Yoga or a Community Outing. These activities will be the same length and duration as the therapeutic horticulture intervention.

Randomization:
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(s)
At Screening/Baseline, 10 weeks (end of intervention), 14 weeks, and 22 weeks for the intervention group and at Screening/Baseline, 10 weeks, 20 weeks (end of intervention, for those who choose to enrol in the intervention after the initial waitlist period), and 24 weeks for the waitlist group:

1. Perceived stress (measured using the Perceived Stress Scale 10 items, PSS-10)
2. Quality of life (EuroQol 5 Dimensions 5 levels, EQ-5D-5L)
3. Wellbeing (ONS-4)

Key secondary outcome(s))
At Screening/Baseline, 10 weeks (end of intervention), 14 weeks, and 22 weeks for the intervention group and at Screening/Baseline, 10 weeks, 20 weeks (end of intervention, for those who choose to enrol in the intervention after the initial waitlist period), and 24 weeks for the waitlist group:
1. Anxiety (Generalized Anxiety Disorder-7 (GAD-7)
2. Sleep quality (PSQI-2)
3. Emotional regulation (Difficulties in Emotion Regulation Scale, DERS-16)
4. Self-esteem (Rosenberg Self-esteem Questionnaire, RSES)

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 on 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 month) or current participation in the same type of nature-based therapy we are evaluating

Participant type(s)
Patient, Population, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

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 behaviours (ICD-11 6B60, 6B61, 6B62, 6B63, 6B64, 6B65, 6B66, 6E65, 6B6Y, 6B6Z)
4. Mental or behavioural 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
01/04/2025

Date of final enrolment
31/07/2026

Locations

Countries of recruitment
Spain

Study participating centre
Day Hospital Centre of Mataró
Carr. de Cirera, 230
Mataró
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08304

Sponsor information

Organisation
Universitat Autònoma de Barcelona

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, Horizonte Europa

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes