ISRCTN13105773 https://doi.org/10.1186/ISRCTN13105773

# GreenME Nature-based therapy evaluation, case 3 - Salus Space

**Submission date**
07/04/2025

**Recruitment status**
Recruiting

**Registration date**
22/08/2025

**Overall study status**
Ongoing

**Last Edited**
22/08/2025

**Condition category**
Other

[ ] 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
Mental health disorders like anxiety and depression are becoming more common worldwide. Traditional treatments can be expensive, have side effects, and aren't always accessible. Spending time in nature has been shown to reduce stress, improve mood, and boost brain function. This study aims to see if nature-based therapies (NBTs), guided by professionals, can improve mental health and be a cheaper alternative to other treatments. The focus is on people who experience significant stress in their daily lives.

Who can participate?
Adults aged 18 to 75 years
Willing and able to join a therapeutic horticulture program
Stress affects their daily life
Either frequently experiences discrimination or prejudices, or has poor sleep, mood, energy levels, sadness, fatigue, or anxiety
Has not participated in a similar nature-based therapy program in the past month

What does the study involve?
Participants will:
Complete questionnaires about their health and wellbeing before the study starts.
Join a 12-week therapeutic horticulture program, with sessions once a week for 120 minutes each.
Complete questionnaires about their experiences and health after the program ends, and again 1 month and 3 months later.
What are the possible benefits and risks of participating?
Benefits:
Contributing to future knowledge about nature-based therapies
Potential personal benefits from the therapy or alternative program
Risks:
Possible physical discomfort during activities
Difficulty completing questionnaires
Where is the study run from? The study involves outdoor activities like gardening, nature observation, and workshops. Participants will work in groups and share their experiences. Each

session includes a welcome, task explanation, practical work, a break, more activities, and feedback.

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?
Dr Michele D'Ostuni, michele.dostuni@unibo.it

# Contact information


### Type(s)
Public, Scientific, Principal investigator

### Contact name
Dr Giuseppina Pennisi

### ORCID ID
https://orcid.org/0000-0001-9377-4811

### Contact details
Viale Giuseppe Fanin, 44
Bologna
Italy
40126
+39 3387038265
giuseppina.pennisi@unibo.it

### Type(s)
Scientific

### Contact name
Dr Michele D'Ostuni

### ORCID ID
https://orcid.org/0000-0002-9246-6099

### Contact details
Viale Giuseppe Fanin, 44
Bologna
Italy
40126
+39 3387038265
michele.dostuni@unibo.it

### Type(s)
Scientific

**Contact name**
Miss Virginia Cioncoloni

**ORCID ID**
https://orcid.org/0009-0004-8600-6071

**Contact details**
Viale Giuseppe Fanin, 44
Bologna
Italy
40126
+39 3341346768
virginia.cioncoloni2@unibo.it

# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**ClinicalTrials.gov (NCT)**
Nil known

**Protocol serial number**
Horizon Europe Grant Agreement 101084198

# Study information

**Scientific Title**
GreenME: Advancing Greencare in Europe: an integrated multi-scalar approach for the expansion of nature-based therapies to improve mental health equity

**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)
approved 11/03/2025, Comitato di bioetica dell'Università di Bologna - Bioethics committee of the University of Bologna (Piazza Verdi, 3, Bologna, 40126, Italy; +39 051 2082043; comitato.bioetica@unibo.it), ref: 0075975

## 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 one session per week over consecutive 12 weeks with a total of twelve sessions. Each session will last 120 minutes. Only low-to-middle physical activities will be allowed during the exposure sessions.

2. Usual Care: The "waitlist" will be used as the control group

Randomitazion process:
Participant assignment to groups will be carried out randomly using a block randomization system.
The allocation sequences will be computer-generated by an independent researcher from the Autonomous University of Barcelona (UAB) & the Open University of Catalonia (UOC) RCore, who will not be involved in participant recruitment.
To ensure the integrity of the study, an academic member from the University of Bologna, not involved in recruitment, will print each sequence on a separate page and place it in a numbered envelope.
Participants will be randomly assigned to one of the following groups:
"Exposed" group  receives the intervention + conventional (non-restrictive) treatments.
"Waiting list" group  receives only standard treatments (e.g., medication, social services).

## Intervention Type
Behavioural

## Primary outcome(s)

Screening: Preliminary assessment to determine participant eligibility.
Baseline: Data collection at the start of the intervention, before exposure.
Follow-up 1: Assessment immediately after the conclusion of the intervention or the "usual care" phase.
Follow-up 2: Assessment one month after the end of the intervention.
Follow-up 3: Assessment three months after the end of the intervention.

1. Activities performed is measured using a tool developed internally by the team at baseline and Follow-up 1
2. Stress interfering with daily life is measured using a tool developed internally by the team at screening
3. Experiences of discrimination is measured using questions indicated in the General Protocol at screening
4. Experiences of poor mental health is measured using a tool developed internally by the team at screening
5. Perceived stress is measured using the Perceived Stress Scale (PSS-10) from baseline to Follow-up 3
6. Quality of life is measured using the EQ-5D-5L from baseline to Follow-up 3
7. General well-being is measured using the ONS-4 from baseline to Follow-up 3
8. Psychological well-being is measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) from baseline to Follow-up 3
9. Anxiety is measured using the GAD-7 from baseline to Follow-up 3
10. Sleep quality is measured using the Pittsburgh Sleep Quality Index (PSQI - 2) from baseline to Follow-up 3
11. Emotion regulation is measured using the Difficulties in Emotion Regulation Scale (DERS-16) from baseline to Follow-up 3
12. Self-esteem is measured using the Rosenberg Self-Esteem Scale (RSES) from baseline to Follow-up 3
13. Depression is measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline, Follow-up 1, Follow-up 2, and Follow-up 3
14. Cost-utility is measured using the Client Service Receipt Inventory (CSRI) at baseline and Follow-up 3
15. Human–nature connection is measured using a tool developed within WP4 of the GreenMe project at baseline and Follow-up 1
16. Perceived benefits from nature exposure is measured using a tool developed within WP4 of the GreenMe project at baseline and Follow-up 3
17. Subjective biodiversity is measured using a tool developed within WP4 of the GreenMe project at Follow-up 1
18. Gender is measured at screening
19. Age is measured at screening
20. Citizenship is measured at baseline
21. Experiences of discrimination is measured using questions from the General Protocol at baseline
22. Stigmatization is measured using the stigma scale from the study "Stigma and self-esteem in manic depression: an exploratory study (SESQ)" by Peter Hayward from baseline to Follow-up 3
23. Discrimination is measured using the Everyday Discrimination Scale (EDS) from baseline to Follow-up 3
24. Highest level of education completed is measured using indicators from the International Standard Classification of Education (ISCED 2011) at baseline
25. Perceived income is measured using a multiple-choice question from the General Protocol at

baseline
26. Sexual orientation is measured using a multiple-choice question from the General Protocol at baseline
27. Medication use is measured using an adaptation of the Client Service Receipt Inventory (CSRI) from baseline to Follow-up 3
28. Exposure to Green Care is measured using a questionnaire developed by the coordination groups of WP4 and WP3 of GreenME from baseline to Follow-up 3
29. Expected treatment is measured using a specific question at baseline
30. Activities performed is measured using a detailed record of activities during the intervention

### Key secondary outcome(s))
There are no secondary outcome measures

### 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)
Resident, 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**
10/04/2025

**Date of final enrolment**
31/07/2026

# Locations

**Countries of recruitment**
Italy

**Study participating centre**
**EtaBeta - Salus Space**
Via Malvezza, 2
Bologna
Italy
40139

# Sponsor information

**Organisation**
Università di Bologna - Dipartimento di Scienze e Tecnologie AgroAlimenatri (DISTAL)

# Funder(s)

**Funder type**
Not defined

**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? |
|---|---|---|---|---|---|
| Participant information sheet | in Italian | | 08/04/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |