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GreenME Nature-based therapy evaluation, case - Battirame

Submission date	Recruitment status	[_] Prospectively registered
09/12/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
13/02/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/11/2026	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

The rising prevalence of mental health disorders, including anxiety and depression, represents a major global health challenge. Although traditional treatments can be effective, they often involve limitations such as high costs, side effects, and restricted accessibility.

In contrast, exposure to natural environments has been shown to reduce stress, improve mood, and enhance cognitive functioning, among other health benefits. Therapeutic interventions delivered in nature (here referred to as nature-based therapies or NBTs) by trained professionals may further amplify these positive effects. Professional guidance can support individuals in developing coping strategies, building resilience, and strengthening their connection with the natural world. However, these therapies also face challenges, particularly related to cost and limited acceptance within the medical community.

This study seeks to strengthen the scientific evidence concerning whether and how NBTs improve mental health and wellbeing, and whether they offer a relatively low-cost alternative to other treatments. Focusing on individuals who experience significant daily stress, the study will examine whether nature-based therapies are more effective than alternative interventions in improving mental health. It will also assess whether NBTs represent a cost-efficient option for treating mental health conditions.

Who can participate?

Participants must meet the following criteria:

1. Aged 18–75 years
2. Willing and able to participate in the therapeutic horticulture program
3. Experience stress that interferes with daily life (as assessed by the screening questionnaire)

Additionally, either:

1. Frequently experience discrimination or prejudice in daily life, or
2. Experience poor sleep quality, poor mood, low energy, sadness, fatigue, or anxiety (as assessed by the screening questionnaire)
3. Have not participated in a similar nature-based therapy program within the past month

What does the study involve?

Participation includes:

1. Completing questionnaires about your health, wellbeing, experiences, and personal

characteristics before the study begins.
2. Taking part in a 12-week therapeutic horticulture program, with one 120-minute session per week, or participating in an alternative program of equivalent duration. Participants will be randomly assigned to either the therapeutic horticulture group or the alternative program.
3. Completing follow-up questionnaires about your experiences, health, and wellbeing at three timepoints: immediately after the program ends, 1 month later, and 3 months later.

What are the possible benefits and risks of participating?
Your participation may help expand scientific understanding of the benefits of nature-based therapies, potentially improving the availability and quality of such programs in the future. You may also personally benefit from the therapeutic horticulture program or from the alternative intervention offered as part of the study. We do not foresee any serious risks from participating in the study. However, it is possible that participants may experience physical discomfort during some of the activities, and may find it difficult to complete the questionnaires.

Where is the study run from?
Eta Beta Cooperativa Sociale (Italy)

When is the study starting and how long is it expected to run for?
The project starts on December, 15 and will run for 11 months.

Who is funding the study?
Horizon Europe

Who is the main contact?
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Contact information

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Scientific, Public

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Additional identifiers

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

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 11/03/2025, Comitato di Bioetica dell'Università di Bologna (Piazza Verdi 3, Bologna, 40126, Italy; +39 (0)51 2082043; comitato.bioetica@unibo.it), ref: 0075975

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Crossover

Purpose
Basic science, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Poor sleep quality, poor mood, low energy levels, sadness, fatigue, anxiety

Interventions
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).

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

Intervention Type
Behavioural

Primary outcome(s)

1. Perceived stress measured using Perceived Stress Scale 10 items (PSS-10) at 1. Screening (before the study starts); 2. Baseline 1 (before the study); 3. Follow-up 1 (end of intervention); 4. Follow-up 2 (1 months after intervention); 5. Follow-up 3 (3 months after the intervention)

2. Quality of life measured using EuroQol 5 Dimensions 5 levels (EQ-5D-5L) at 1. Screening (before the study starts); 2. Baseline 1 (before the study); 3. Follow-up 1 (end of intervention); 4. Follow-up 2 (1 months after intervention); 5. Follow-up 3 (3 months after the intervention)

3. Wellbeing measured using ONS-4 at 1. Screening (before the study starts); 2. Baseline 1 (before the study); 3. Follow-up 1 (end of intervention); 4. Follow-up 2 (1 months after intervention); 5. Follow-up 3 (3 months after the intervention)

Key secondary outcome(s)
1. Anxiety measured using General Anxiety Disorder-7 (GAD-7) at 1. Baseline 1 (before the study); 2. Follow-up 1 (end of intervention); 3. Follow-up 2 (1 months after intervention); 4. Follow-up 3 (3 months after the intervention)

2. Sleep quality measured using Pittsburgh Sleep Quality Index-2 (PSQI-2) at 1. Baseline 1 (before the study); 2. Follow-up 1 (end of intervention); 3. Follow-up 2 (1 months after intervention); 4. Follow-up 3 (3 months after the intervention)

Completion date
15/11/2026

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

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex
All

Total final enrolment
48

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
15/12/2025

Date of final enrolment
08/05/2026

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
University of Bologna

ROR
https://ror.org/01111rn36

Funder(s)

Funder type

Funder Name
Horizon 2020 Framework Programme

Alternative Name(s)
EU Framework Programme for Research and Innovation H2020, Horizon 2020, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan	version 1.3		09/11/2026	No	No