# The effect of a therapeutic nature-based intervention on stress in people with mental ill-health

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>		
01/05/2025	Recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/06/2025	Ongoing	Results		
Last Edited	Condition category	Individual participant data		
28/05/2025	Mental and Behavioural Disorders	[X] Record updated in last year		

#### Plain English summary of protocol

Background and study aims

It is thought that urban green and blue spaces provide a range of benefits for people and nature. The GreenME study aims to find out more about the mental health and well-being effects of nature-based therapy programmes for adults with a mental health condition.

#### Who can participate?

People who have been referred to, or have self-referred, because of stress in daily life, to one of two community-based organisations that provide nature-based interventions.

#### What does the study involve?

Participants will attend the nature-based intervention once a week for ten weeks, with each session lasting 2 hours. There are two areas involved in this study, and the activities depend on the location. Area 1 includes activities such as going for a nature walk, nature craft, tree identification, cloud gazing, whittling, foraging, and focusing on breathing, letting go of stress and deepening connection to nature and each other. In Area 2, participants are offered opportunities to experience ocean and coastal activities. Activities include surfing, walking on the beach, coastal care work, beach art, foraging and mindfulness exercises.

People who are part of the study will complete a series of four questionnaires throughout their programme. After everybody has done an initial questionnaire, two groups will be created. One will be the 'straight away' group, who will start the intervention without delay. People in this group will complete additional questionnaires at the end of the programme, 4 weeks after that, and then a final one 8 weeks after that (3 months after the programme finished). Those in the waiting group will wait about 10-12 weeks and then complete a questionnaire just before starting their nature-based intervention. There will be a questionnaire at the end of the 10-week programme, and then a final 4 weeks after that. Both groups will complete four sets of questionnaires in total.

What are the possible benefits and risks of participating?

People who experience the intervention will be exposed to natural environments that might be

beneficial. In the longer term, it is hoped that this study will contribute to the understanding more about the impact of nature-based interventions on mental health and wellbeing. The study is low risk, but it does involve thinking about mental and physical health, which for some people may be difficult.

Where is the study run from? The University of Salford, UK

When is the study starting and how long is it expected to run for? September 2023 to August 2027. The study recruitment starts in May 2025 and is expected to run until July 2026.

Who is funding the study?
The Horizon Europe Research and Innovation Programme, EU

Who is the main contact? Prof Penny Cook, School of Health and Society, University of Salford, P.A.Cook@salford.ac.uk

#### Study website

https://greenme-project.eu/

## Contact information

#### Type(s)

Scientific, Principal Investigator

#### Contact name

Prof Penny Cook

#### **ORCID ID**

https://orcid.org/0000-0001-6435-8050

#### **Contact details**

School of Health and Society, Allerton Building, University of Salford Salford United Kingdom M6 6PU +44 (0) 161 295 6052 p.a.cook@salford.ac.uk

## Type(s)

Public

#### Contact name

Dr Sarah Knight

#### **ORCID ID**

https://orcid.org/0000-0002-9977-8810

#### Contact details

School of Science, Engineering and the Environment, Newton Building, University of Salford Salford United Kingdom M5 4WT +44 (0)161 295 5000 s.j.knight1@salford.ac.uk

## Additional identifiers

#### **EudraCT/CTIS** number

Nil known

#### IRAS number

#### ClinicalTrials.gov number

Nil known

#### Secondary identifying numbers

Horizon Europe Grant Agreement 101084198; Salford Worktribe Ref 1344901

# Study information

#### Scientific Title

The effect of therapeutic nature-based interventions on stress reduction in people with mental ill-health: a randomised controlled trial versus treatment as usual

#### Acronym

GreenME

## Study objectives

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

## Ethics approval required

Ethics approval required

## Ethics approval(s)

Approved 07/05/2025, University of Salford Health and Society Research Ethics Committee (Maxwell Building, The Crescent, Salford, M5 4WT, United Kingdom; +44 (0)161 295 5000; ethics@salford.ac.uk), ref: 2025-4552-6075

## Study design

Two-centre interventional randomized controlled trial with analysts blinded to treatment group

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

#### Study setting(s)

Charity/Voluntary sector, Community

#### Study type(s)

Treatment

#### Participant information sheet

See study outputs table

#### Health condition(s) or problem(s) studied

Reduction in stress in those with self-reported moderate-to-high perceived stress levels

#### **Interventions**

Adults experiencing significant stress in their daily life and have been referred, or have self-referred, due to poor mental health, will be randomised to either receive a nature-based intervention straight away or be placed on a waiting list.

The project will use block randomisation. Sequences for all interventions will be computergenerated by an independent researcher from the University of Barcelona's Core Team, not involved with participant recruitment and allocation.

Treatment is in groups of 10-12 participants and involves 10 weeks of weekly 120-minute sessions. Treatment depends on geographical location. Area 1 includes activities such as going for a nature walk, nature craft, tree identification, cloud gazing, whittling, foraging, and focusing on breathing, letting go of stress and deepening connection to nature and each other. Sessions are adapted to be accessible for those with complex, overlapping health and mobility needs. In Area 2, participants are offered opportunities to experience ocean and coastal activities, whilst being supported by trained professionals and trained volunteers. Activities include surfing, walking on the beach, coastal care work, beach art, foraging and mindfulness exercises.

After 10 weeks, those allocated to the waiting list will receive the intervention. Whilst on the waiting list, participants will receive usual care.

#### Intervention Type

Behavioural

#### Primary outcome measure

Psychological stress measured using the Perceived Stress Scale (PSS-10) at: For exposure group: Baseline, Follow up 1 (week 10); Follow up 2 (week 14); Follow up 3 (week 22)

For waitlist group: Baseline, Follow up 1 (week 10); Follow up 2 (week 20); Follow up 3 (week 24)

#### Secondary outcome measures

Measured at:

For exposure group: Baseline, Follow up 1 (week 10); Follow up 2 (week 14); Follow up 3 (week 22)

For waitlist group: Baseline, Follow up 1 (week 10); Follow up 2 (week 20); Follow up 3 (week 24)

- 1. Quality of Life measured using the EuroQol 5 Dimensions 5 levels (EQ-5D-5L)
- 2. Wellbeing measured using four measures of the Office for National Statistics version 4 (ONS-4)
- 3. Nature connectedness measured using the Nature Connection Index (NCI)

#### 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 is significantly or very significantly elevated
- 4. Either: often or very often experiences of discrimination or prejudices in daily life OR Yesexperiencing 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

#### Participant type(s)

Other

#### Age group

Mixed

#### Lower age limit

18 Years

#### Upper age limit

75 Years

#### Sex

Both

#### Target number of participants

156

#### Key exclusion criteria

- 1. Intellectual disability (ICD-11 6A00)
- 2. Phobias that can highly impact the capacity to benefit from the evaluated interventions, such as social and insect-related phobias (ICD-11 6B02, 6B03, 6B04)
- 3. Dissociative behaviours (ICD-11 6B60, 6B61, 6B62, 6B63, &b64, 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 the evaluated interventions or that increase the potential to become difficult cases to handle by project staff (ICD-11 MB23.0, MB23.R, MB23.S)

#### Date of first enrolment

28/05/2025

#### Date of final enrolment

31/07/2026

## **Locations**

## Countries of recruitment

England

**United Kingdom** 

Wales

## Study participating centre Northern Roots (Oldham) Ltd

Oldham Council Alexandra Park Offices Kings Road Oldham United Kingdom OL8 2BH

## Study participating centre

**Tonic Surf** 

68 Derwen Gardens Adpar Ceredigion United Kingdom SA38 9PS

# Sponsor information

## Organisation

University of Salford

## Sponsor details

The Old Fire Station, The Crescent Salford England United Kingdom M5 4WT +44 161 295 5000 V.Halliwell@salford.ac.uk

#### Sponsor type

University/education

#### Website

https://www.salford.ac.uk/

#### ROR

https://ror.org/01tmqtf75

# Funder(s)

#### Funder type

Government

#### **Funder Name**

UK Research and Innovation

#### Alternative Name(s)

**UKRI** 

#### Funding Body Type

Government organisation

#### Funding Body Subtype

National government

#### Location

United Kingdom

## **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 GreenME study. We plan to publish the findings through a report to the European Commission, as peer-reviewed publications in academic journals and present them at academic conferences. The results of the study will be available on the project website. We will share our findings to all the project partners involved in the research programme, so they can also be shared with participants and publicised on social media and will help inform future policy and practice.

## Intention to publish date

01/05/2027

#### Individual participant data (IPD) sharing plan

We will deposit processed, grouped and anonymised data (and their metadata) in a trusted repository (either http://ddd.uab.cat, https://dmp.csuc.cat, https://zeonodo.org). This data will be shared in standard format (.csv, .doc, .pdf, .jpg, or .txt). When making this data public, we will also create a Digital Object Identifier (DOI) that will be assigned to this dataset. Metadata for this dataset will be created using the Dublin Core standard (see https://www.dublincore.org

/specifications/, or equivalent metadata standard), a generic standard appropriate across disciplines. Keywords will be included in the metadata following an established thesaurus (e.g., MESH terms, or similar) to allow for discoverability. Processes for storing and accessing this data will be reviewed by the Universitat Autònoma de Barcelona (UAB) ethics committee (GreenME lead partner) before publication. The data will be maintained and available for at least 5 years following the end of the study.

- The following information will be shared only upon request:
- o The processed data files that support results published in scientific publications.
- o Related documentation (i.e., metadata, codebooks, ontologies) related to the data; and
- o The analysis code to reproduce and validate the quantitative results of published articles. This code will be provided in the coding language of the software used to analyse the data, which will also be specified.
- The following data are not expected to be shared:
- o The original raw data collected from the evaluation of nature-based therapy programs in WP3.
- o Any non-anonymized digital research data (e.g., any data containing personal identifying information).
- o Qualitative data, such as sound recordings or transcripts

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request:

Dr Margarita Triguero-Mas, GreenME Scientific Co-ordinator, Faculty of Health Sciences, Universitat Oberta de Catalunya, mtrigueromas@gmail.com

#### IPD sharing plan summary

Stored in non-publicly available repository, Available on request

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			27/05/2025	No	Yes
Participant information sheet			27/05/2025	No	Yes