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Nature-based activities to support mental ill health

Submission date
20/06/2025

Recruitment status
No longer recruiting

Registration date
04/07/2025

Overall study status
Ongoing

Last Edited
28/01/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
There is increasing evidence that taking part in activities in nature, such as gardening or conservation, has positive impacts on people's health and well-being. These types of activities can be offered to people through social prescribing, where people can be referred to community activities as part of their treatment. Although there are a large number of nature-based social prescribing projects, few have been evaluated using the most robust methods. Healthcare commissioners are increasingly seeking high-quality evidence of the effectiveness of nature-based activities. Randomised controlled trials (RCTs) are widely accepted as the most reliable way to demonstrate effectiveness. This type of evaluation will support more confident decision-making around funding and help ensure that people with mental health needs are referred to the most appropriate interventions for them.
This study will be a pilot RCT. Before undertaking a full trial, it is important to ensure the plans for that research are feasible, appropriate and acceptable, so that the outcomes of the RCT will be meaningful. A pilot allows us to test the proposed research processes (for example, that we are able to recruit enough people and that the questionnaires used to measure impact are appropriate). We will collect quantitative data on impacts and speak to participants and the nature-activity providers to understand what works well and what could be improved. The pilot will recruit people to the study and randomise them to receive a 6-week nature-based activity or to a comparison group. Changes in their mental health, wellbeing, loneliness and health services use will be compared between these two groups. The comparison group will then also be offered the chance to take part in nature-based activities.
The outcome of the study will be a detailed plan for a future RCT which will assess the effectiveness and cost-effectiveness of nature-based activities for people with mental ill-health.

Who can participate?
Adults aged 18 years and over with mild to moderate depression and/or anxiety who live within travelling distance of the activity sites

What does the study involve?
Adults living with mild to moderate depression and/or anxiety will be invited to join the study via targeted emails or texts from their GPS, referrals from link workers who work with the activity providers, social media advertisements, or they may hear about the study informally via friends

and family. Participants will be randomly allocated to either the intervention group or the wait-list control group. Once randomised, the participants will be asked to fill in a set of baseline questions on their mental health, wellbeing, loneliness and health service use, and on their personal characteristics. The intervention group will take part in a 3-hour session of nature-based activities once a week for 6 weeks. All participants will then be asked to fill in the same questions asked at baseline when the activities end, and then again 6 weeks later. Once all the data has been collected, the wait list control group will be able to take part in the nature-based activities. Participants will also be invited to take part in focus groups to help us understand their experiences.

What are the possible benefits and risks of participating?
Participants in both groups will receive a 6-week nature-based programme of activities (an approximately 3-hour session once a week) designed to help manage mild to moderate depression and/or anxiety.
Potential risks of the study may include distress linked to reflection on the issues raised by the data collection tools. All activities will take place outdoors, and there may be inclement weather and minor injuries related to walking and the use of gardening equipment. Participants may enjoy and feel benefit from the nature-based activities they do in the intervention, and not want these to end after the research study.

Where is the study run from?
European Centre for Environment and Human Health, University of Exeter, Faculty of Health and Life Sciences (UK)

When is the study starting and how long is it expected to run for?
October 2024 to March 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
1. Prof. Ruth Garside, R.Garside@exeter.ac.uk
2. Dr Rebecca Lovell, r.lovell@exeter.ac.uk

Contact information

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Principal investigator

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Additional identifiers

Central Portfolio Management System (CPMS)
57053

Integrated Research Application System (IRAS)
330630

National Institute for Health and Care Research (NIHR)
208091

Study information

Scientific Title
Nature on prescription to support mental ill health (GREENGAGE): a pilot randomised controlled trial and process evaluation

Acronym
GREENGAGE

Study objectives
Primary study hypothesis:
The mild to moderate depression and/or anxiety of people receiving nature-based therapeutic activities improves to a greater degree than a control group not receiving the activities.

Study feasibility and testing hypotheses:
1. The study recruitment strategies and enrolment procedures are acceptable and feasible
2. The intervention is acceptable to participants and delivery organisations
3. The process of recruitment is feasible
4. The process of allocation to intervention or waitlist control group is acceptable and feasible
4. Retention of the control group (waitlist) is sufficient
5. Adherence to and fidelity of trial procedures are sufficient

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/05/2025, Wales REC7 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, United Kingdom; +44 (0)2922 941107, +44 (0)2922 940968; Wales.REC7@wales.nhs.uk), ref: 25/WA/0125

Study design
Randomized; Both; Design type: Treatment, Complex Intervention, Other, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mental health

Interventions
The participation process for individuals will be:
1. Reading the project PIS.
2. Opportunity to discuss the project with the research team.
3. Initial suitability for location and timing of nature-based activities.

4. Completion of the screening tool to determine eligibility.
5. Completion of the consent form
6. Completion of the baseline questionnaires (T0) for all participants (Participant characteristics; Mental health and wellbeing measures; Health service use questionnaire).
7. Random allocation to either the intervention group (nature-based activities) or the control group (usual care, wait list).
8. Those allocated to the intervention group will participate in a 6-week programme of nature-based activities. An initial optional induction session prior to the first group session will also be available.
9. Completion of questionnaires for all participants (6 weeks post-intervention start [T1] and 12 weeks post [T2]): (Mental health and wellbeing measures; Loneliness measure; Health service use questionnaire).
10. Participation in a focus group discussion about their experience of the pilot trial (optional).
11. Those allocated to the control group will be offered the opportunity to take part in a 6-week programme of nature-based activities after the follow-up period.

Intervention Type
Behavioural

Primary outcome(s)
1. Anxiety is measured using the Generalised Anxiety Score scale (GAD-7) at T0 (baseline), T1 (end of intervention), and T2 (6-week follow-up).
2. Depressive symptoms are measured using the Patient Health Questionnaire scale (PHQ-9) at T0 (baseline), T1 (end of intervention), and T2 (6-week follow-up).

Key secondary outcome(s))
1. Mental wellbeing is measured using the short Warwick-Edinburgh Mental Wellbeing Scale (sWEMWBS) at T0 (baseline), T1 (end of intervention), T2 (6-week follow-up)
2. Wellbeing is measured using the ONS4 scale at T0 (baseline), T1 (end of intervention), and T2 (6-week follow-up)
3. Loneliness is measured using both:
3.1. The UCLA Three-Item Loneliness Scale
3.2. A single-item direct measure, asking "How often do you feel lonely?" both at T0 (baseline), T1 (end of intervention), and T2 (6-week follow-up)
4. Health services use/economics is a bespoke measure at T0 (baseline), T1 (end of intervention), and T2 (6-week follow-up)

Process measures:
1. Decliner data measured using bespoke questionnaire at identified point of decline to participate/drop out at any time post randomisation
2. Intervention Group participant experience assessed using Focus Groups at Post-intervention (T1)
3. Waitlist control group participant experience assessed using Focus Groups before they participated in the waitlist intervention
4. Nature-Based Provider experience assessed using Focus Groups after the wait list intervention has taken place.

Completion date
31/03/2026

Eligibility

Key inclusion criteria
1. People aged 18 years and over
2. People with mild to moderate depression and/or anxiety assessed by scores of 10-19 on the Patient Health Questionnaire (PHQ-9) and/or 5-14 on the Generalised Anxiety Disorder assessment (GAD-7)
3. Ability to give informed consent to written information sheets and consent forms
4. Participants may be on any current treatment for mild to moderate depression and/or anxiety, or none

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. People with severe depression and/or anxiety (as assessed by scores of 20 or more on the PHQ-9 and/or 15 or more on GAD-7)
2. People unable to understand written and verbal instructions in English
3. Those with serious physical impairment that would prevent participation in even adapted nature-based activities (such as walking, gardening, pond dipping)
4. Actively suicidal or psychotic (as assessed by the mood screener – see later details)

Participants will need to have a good understanding of English to participate given that the intervention instructions, including safety instructions related to specific activities or tool use, will be given in English by the nature-based providers on the day. As these are small VCSE groups, it is not possible for staff to accommodate other languages.

Date of first enrolment
16/06/2025

Date of final enrolment
17/11/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Exeter
Stocker Road
Exeter
England
EX4 4PY

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
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EX2 5DW

Sponsor information

Organisation
University of Exeter

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3	02/07/2025	02/07/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes