Nature Based Activities to Support Mental Ill Health (GREENGAGE): A Pilot Randomised Controlled Trial and Process Evaluation

GREENGAGE

IRAS Number:	330630
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Funders Number:	NIHR208091

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University of Exeter

Signature Page

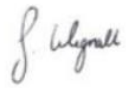
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol. The trial will adhere to the principles of Good Clinical Practice (GCP), the UK Policy Framework for Health and Social Care Research, and all applicable ethical and regulatory requirements, including those set out by the Health Research Authority (HRA) and the Research Ethics Committee (REC).

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: Date: 01/04/25



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Chief Investigator:

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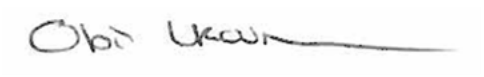
Statistician:

Signature:  06/02/2025

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Additional Research Team Members	Prof Anne Spencer (health economics), Prof Katrina Wyatt (complex interventions), Merryn Kent (Trial administrator)
Statistician	Prof Obioha C Ukoumunne

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List of Abbreviations

GP: General Practitioner

GSP: Green Social Prescribing

HEPE: Health and Environment Public Engagement

MH: Mental Health

NHS: National Health Service

PPI/E: Public and Patient Involvement/Engagement

RCT: Randomised Controlled Trial

SP: Social Prescribing

TSC: Trial Steering Committee

VCSE: Voluntary and Community Sector Enterprises

Trial Summary

This external pilot randomised controlled trial will test and finalise the processes for undertaking a definitive randomised controlled trial (RCT) to assess the effectiveness and cost-effectiveness of a group, nature-based intervention in addition to usual care, versus usual care alone, for adults with mild-to-moderate depression and/or anxiety.

Trial Title	Nature-Based Activities to Support Mental Ill Health (GREENGAGE): A Pilot Randomised Controlled Trial and Process Evaluation
Internal ref. no. (or short title)	GREENGAGE
Trial Design	Pilot RCT with embedded qualitative process evaluation
Trial Participants	Adults (aged ≥18 years) with mild-to-moderate depression and/or anxiety
Planned Sample Size	84 participants (42 in each arm)
Treatment duration	6 weeks
Follow up duration	12 weeks post-intervention (approximately 14 weeks post-randomisation, depending on pace of recruitment)
Planned Trial Period	April 2025 to 31st March 2026 *NB: The formal end of the study is marked by the end of the funded period.*
Primary Objectives	To establish recruitment (percentage of those screened who participate) and retention rates of participants in intervention and control groups.

Funding and Support in Kind

FUNDER(S)	**FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN**
NIHR NIHR PRP Grange House 15 Church Street Twickenham TW1 3NL 020 3692 7986 prp@nihr.ac.uk	£373,057.53 secured

Role of Trial Sponsor and Funder

Ther University of Exeter is the sponsor of this study. The study sponsor will ensure that the research team has access to resources and support to deliver the research as proposed and that responsibilities for management, monitoring and reporting of the research are in place prior to the study commencing. The sponsor will ensure that there is agreement on recording, reporting and reviewing significant developments as the research proceeds and approve any modifications to design, obtaining requisite regulatory authority approval. The sponsor will assume responsibility for operating the management and monitoring systems of the research.

Prior to the study commencing the sponsor will be satisfied that:

- The research will respect the dignity, rights, safety and well-being of participants and the relationship with healthcare professionals.
- Where appropriate the research has been reviewed and approved by an NHS Research Ethics Committee and/or the Health Research Authority Approval Programme.
- The Chief Investigator, and other key researchers have the requisite expertise and have access needed to conduct the research successfully.
- The arrangements and resources proposed for the research will allow the collection of high quality, accurate data and the systems and resources will allow appropriate data analysis and data protection.
- Organisations and individuals involved in the research agree the division of responsibilities between them.
- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted to significant developments during the study, whether in relation to the safety of individuals or scientific direction.
- There are arrangements for the conclusion of the study including appropriate plans for the dissemination of findings.

The sponsor plays no role in the design of this study and will have no role in data analysis or interpretation or writing up of findings of the study.

Roles and Responsibilities of Trial Management Committees/Groups & Individuals

The trial management group meets monthly to ensure that the practical details of the trial are progressing well and that everyone in the team understands them. They provide expert advice about trial design and processes and will contribute to data analysis, interpretation and writing manuscripts.

The Trial Steering Committee (TSC) will be composed of an independent chairperson with expert knowledge in the subject area, an independent statistician, Patient and Public Involvement (PPI) representative(s) and at least one other independent professional member. The Chief Investigator and another member of the trial management group will join the TSC as non-independent members. Observers will be invited to attend TSC meetings but will not be voting members (e.g. trial manager, trial statistician, health economist).

The role of the TSC is to monitor and supervise the progress of the trial. The TSC will meet prior to recruitment commencing and approximately 6-monthly thereafter.

Protocol Contributors

This protocol has been developed collaboratively with input from a multidisciplinary team of experts, ensuring comprehensive consideration of all aspects of the study design and implementation:

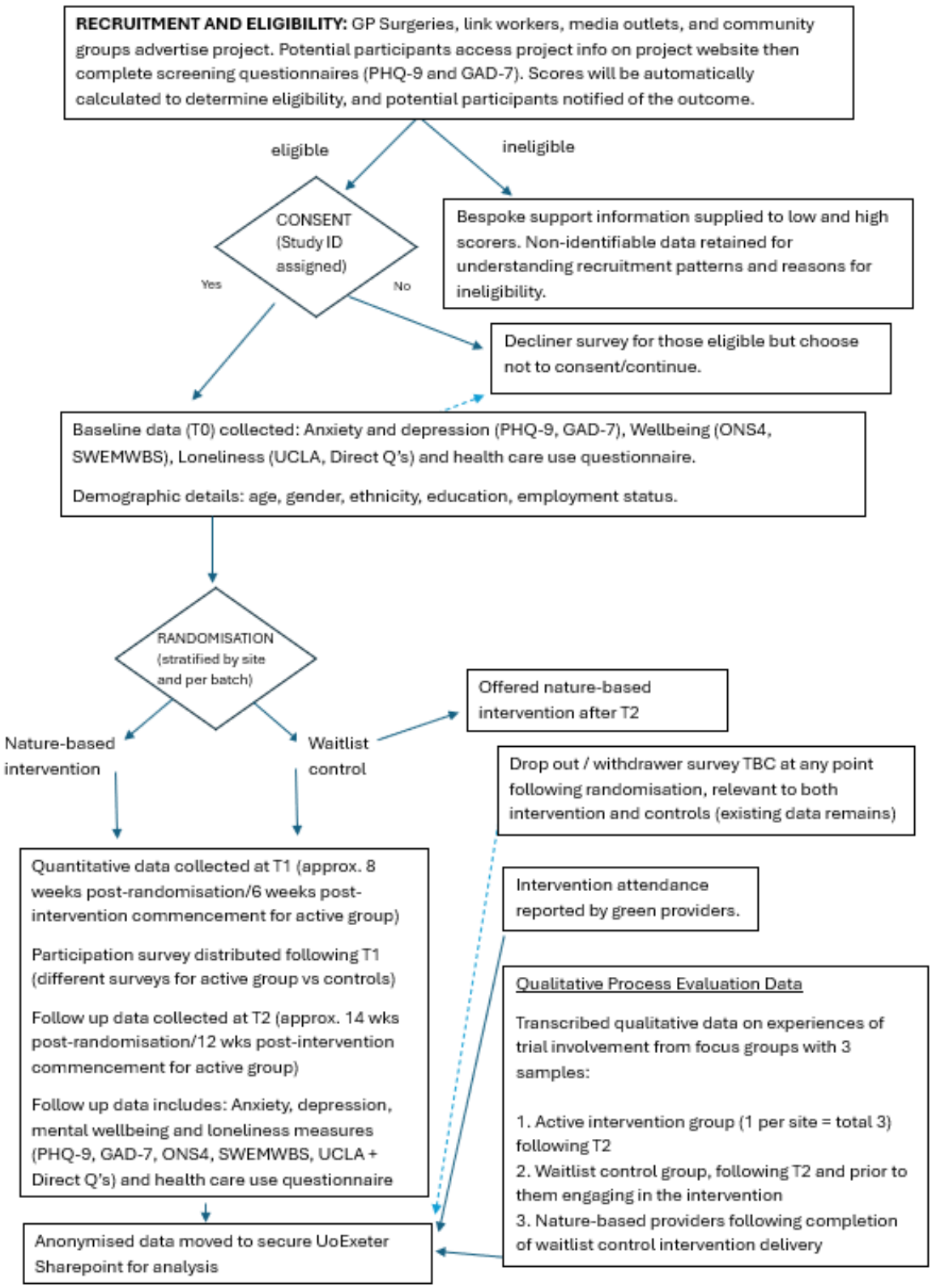
- Professor Ruth Garside (Chief Investigator): Expertise in connections between environmental interventions and health, previously led projects related to developing nature-based interventions, evaluating green social prescribing and feasibility study for nature-based interventions for mental ill health.
- Katie Gibbs: Research Fellow, specialist in wellbeing science and qualitative research. Responsible for creating data collection tools and qualitative data collection, informing development of the project website, ensuring adherence to the protocol, and generally overseeing day-to-day operations.
- Dr. Rebecca Lovell: Specialist in the links between nature and health, environmental interventions, inequalities, evaluation. Contributing to the conceptual framework and intervention design, delivery of the pilot.
- Dr Kerryn Husk: Expert in social prescribing and health services. Advising on pathways for recruitment and integration with community-based interventions, delivery of the pilot.
- Professor Siobhan Creanor: Director of the Clinical Trials Unit. Providing guidance on trial design, randomisation, and data management.
- Professor Anne Spencer: Health economist. Contributing to the design and implementation of the economic evaluation component.
- Professor Katrina Wyatt: Specialist in complex interventions. Providing expertise in process evaluation and stakeholder engagement.
- Professor Obioha C. Ukoumunne: Statistician. Responsibilities including study design, sample size calculation, randomisation procedures, analysis plan development and data analysis.

KEY WORDS: Nature-based interventions, nature-based activities, green social prescribing, mental health, pilot randomised controlled trial, process evaluation

Trial Flow Chart

The flow diagram below provides a schematic overview of the trial, detailing the patient journey and trial pathway.

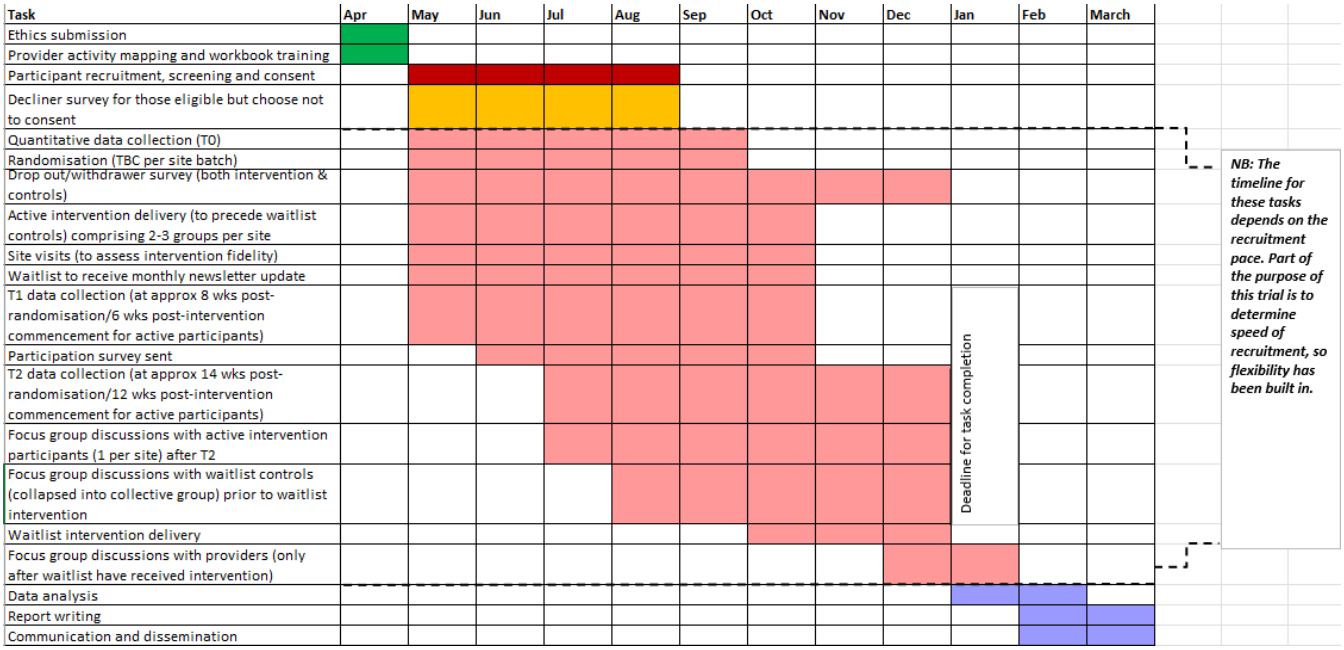
Data Flow through GREENGAGE Pilot Trial



All participant questionnaires will be completed at three time points: at baseline (T0), at approximately 8 weeks post-randomisation (T1) or immediately after participants receive the 6-week intervention, and at a further 6 weeks follow up (T2).

The exact timing between T0 and T1 will depend on the pace of recruitment for each group. A key part of this pilot trial is to determine the speed of recruitment. We anticipate that the commencement of the intervention will begin two weeks post-randomisation per batch. T1 will strictly be conducted once participants have completed the six-week intervention, and T2 at a further 6-week follow-up. This approach ensures that follow-up assessments are not conducted while participants are still receiving the intervention, while also avoiding unnecessary delays if recruitment progresses faster than anticipated.

This timing strategy reflects our intention to balance methodological rigour with practical feasibility, acknowledging that part of this study's aim is to explore the logistical challenges of recruitment and follow-up in this context. This is depicted on the GANTT chart below.



Trial Overview

Background

Common mental health conditions, such as depression, anxiety, and stress, affect up to 15% of the UK population at any time, and one in four people experience a mental health problem at some point in their lives. The shift towards personalised care for people with mental ill health includes facilitating access to community-based sources of support. Pathways such as social prescribing (SP) link people to social or community-based resources – including nature-based activities – which have the potential to improve health and wellbeing. While there are numerous

organisations in the UK providing nature-based activities, there are few studies using the most reliable methods to assess their effectiveness for people with mental ill-health.

Rationale

This external pilot randomised controlled trial will test and finalise the processes for undertaking a definitive randomised controlled trial (RCT) to assess the effectiveness and cost-effectiveness of a group, nature-based intervention in addition to usual care, versus usual care alone, for adults with mild-to-moderate depression and/or anxiety.

Aims and Objectives

We aim to test and finalise the processes for undertaking a definitive, fully-powered RCT of the effectiveness and cost-effectiveness of a nature-based intervention in addition to usual care versus usual care alone (wait-list control group) for adults with mild-to-moderate depression and/or anxiety.

Methods

This is an external pilot RCT of group, nature-based activities for people with mild-to-moderate depression and/or anxiety. We aim to recruit 84 people via GPs, community groups and social media advertising who, following screening for mild-to-moderate depression and/or anxiety, will be randomised to receive either a 6-week nature-based activity course at one of three locations in the south west of England, together with usual care, or receive usual care alone. Randomisation will be stratified by location. We will collect data on participants' mental health and wellbeing using the Office of National Statistics "Personal Wellbeing" (ONS4); the short version of the Warwick–Edinburgh Mental Wellbeing Scale (sWEMWBS); the Patient Health Questionnaire (PHQ-9); General Anxiety Disorder measure (GAD-7); and the Three-Item Loneliness Scale. These assessments will be administered prior to the randomisation and at 6 and 12 weeks after intervention start (or equivalently at approximately 8- and 14-weeks post-randomisation). Data will be collected online using a secure service. Health service use data will also be collected. We will use decliner and participant surveys to understand factors that affect participation and focus group discussions to understand the experiences of those participating in the pilot to help refine the process for the future trial.

Timelines for delivery

April 2025 – 31st March 2026

NB: The formal end of the study is marked by the end of the funded period.

Anticipated Impact and Dissemination

A key outcome will be the development of a detailed protocol for a future definitive RCT of nature-based activities for people with mild-to-moderate depression and/or anxiety. In addition, we will write up the results of the pilot study for publication in an open access journal and produce a plain language summary to be shared with participants, members of the public and other stakeholders.

Extended Background

Mental health need and new models of care

Common mental health conditions, such as depression, anxiety, and stress, affect up to 15% of the UK population at any time, and one in four people experience a mental health problem at some point in their lives. Anxiety and depression are the most commonly reported mental health concerns, and these often present together (Nimmons et al, 2022). Mental ill health accounts for nearly a third of general practice consultations (Mental health Foundation 2016) and is a leading cause of workplace absenteeism (ONS, 2022). People suffering from poor mental health are at risk of dying 15-20 years earlier than people with good mental health (Mental Health Taskforce, 2016). The burden of poor mental health falls disproportionally on the most socio-economically deprived and marginalised groups. Poverty increases the risk of mental ill health and can be both a causal factor and a consequence (Fell & Hewstone 2015). The costs of mental health problems to the economy are approximately £105 billion every year (Department of Health, 2011).

There is increasing interest in providing personalised care for people with mental ill health, including facilitating access to community-based sources of support. Having been pivotal to the 2017 Alma Ata Declaration on Primary Health Care (Department of Health, 2018), there is recognition that social and other non-medical factors strongly influence health. A recent study involving participants from very low-income communities and healthcare professionals practising in these neighbourhoods, found high levels of poverty-related distress. People felt stigmatised in seeking support for their poor mental health, which was mostly structural in its origin. GPs felt frustrated by the lack of treatment options, and that those available focussed on addressing single issues in isolation (Thomas et al 2019).

'Social prescribing' is an alternative, community-based, approach. In the NHS (National Health Service) Long Term Plan, social prescribing (SP) is seen as a key component of personalised care (Department of Health, 2018). SP consists of a process of supporting individuals through linking them to social or community-based activities or resources – such as volunteering, nature-based activities, or arts activities, choirs - which have the potential to improve health and wellbeing. It is defined by the UK Social Prescribing Network as a means of enabling GPs and other frontline healthcare professionals to refer patients to a link worker. This provides patients with a face-to-face conversation during which they can learn about the possibilities and design their own personalised solutions (i.e., 'co-produce' their 'social prescription') so that people with social, emotional or practical needs are empowered to find solutions which will improve their health and wellbeing, often using services provided by the voluntary and community sector (The Social Prescribing Network, 2019).

Social Prescribing and Nature-Based Activities

There has been a significant expansion in the development and delivery of nature-based therapeutic interventions aimed at treating and/or supporting mental health (e.g. gardening, conservation activities, green walks, care farming), and accessed through SP as well as through self-referral, and community links (Haywood et al 2024). The types of activity offered by nature-based providers vary, including whether therapeutic aspects, such as formal counselling or therapy, or other intervention components, such as skills learning or creative activities, are also included. There are few high-quality studies, using robust methods, that have assessed

effectiveness for people with mental ill-health. Our 2021 work on nature-based social prescribing identified 59 projects in four case study areas; however, only two of the 59 had published evaluations – both using an uncontrolled, before-and-after study design (Garside et al 2021). While some pilot studies have used an RCT design, these remain few. A recent systematic review of the effects of nature prescriptions on cardiometabolic and mental health, and physical activity confirmed this, with most studies in those with mental health need not using RCT designs, and those that did being small and not studying populations with mild-to-moderate depression (Nguyen et al, 2023).

Uptake of nature-based social prescribing is likely to be socially patterned, influenced not just by availability, but also by a range of individual variables including age, gender, education level, employment status, ethnicity, and disability. Community, neighbourhood and geographical factors including local infrastructure such as transport also influence uptake. Recent data suggest SP is offered to around five times as many people living in the least deprived neighbourhoods as in the most deprived (Jani et al 2020). However, there is little good evidence about whether nature-based, or other, social prescribing activities can address health inequalities, or how well these are serving marginalised groups.

Furthermore, nature-based activities are themselves complex interventions, relying on chains of stakeholders who refer to or deliver the varied activities, which are delivered in a range of localities, with complex relationships between group members undertaking them as well as with the facilitators. To achieve benefit through social prescribing, while avoiding exacerbating inequalities in health, patients need to be appropriately identified, referred and matched to suitable available nature-based activity offers.

Rationale

Previous work by the team

Through several programmes of research (MRC MR/S002286/1 – the development of a nature-on-prescription intervention for common mental health conditions, and NIHR203452 / IRAS317076 - a development and feasibility study for an RCT of nature-based social prescribing for mental health) we have clarified the specific components and active mechanisms associated with nature-based interventions and explored working with nature-based providers. We have followed guidance from the MRC on the core elements of complex intervention development and testing to refine the intervention: a) consider the impact of context, b) develop and test a programme theory, c) consult stakeholders, d) identify key uncertainties, e) provide opportunities to refine our intervention and f) include economic considerations throughout (Skivington et al 2021).

In 2022-2023 we undertook a single-arm feasibility study as part of preparations for designing and delivering a randomised controlled trial of nature-based social prescribing, to assess the effectiveness and cost-effectiveness for people with mild-moderate depression people. Twenty-nine participants took part in six weeks of 3-hour NBSP interventions for six weeks, led by two different organisations in SW England.

Results from our feasibility work have informed our protocol for the next stage in a number of ways. We found that working with community-based nature-based providers requires considerable researcher liaison, support and communication and this has time and resource

implications for future work. We also found that recruitment of patients with mild-to-moderate depression and/or anxiety through primary care was initially slow to set up due to NHS winter workload pressures. This route, however, has proved valuable as it provided good conversion rates from eligible potential participants approaching the project to actual participants. Additional routes to recruitment, which were added as an ethics amendment for the feasibility study, will be used from the start and use the same screening tool as previously to assess eligibility. In addition, we have a better understanding of the support that the participants need – such as more information about where they are going and what they will be doing, and the option of an induction visit – to help refine our processes. We also took advice from our PPI group about the nature of the control group (specifically to use a wait list control) and adding measures on loneliness to our outcome measures.

Despite important learning from the feasibility work, there remain several uncertainties, including whether patients with mild-to-moderate depression find a RCT of nature-based interventions using a wait list control acceptable. As a next step, we, therefore, propose a pilot randomised controlled trial with associated qualitative process evaluation component. This underpinning work is critical to ensure that any definitive, fully powered RCT is deliverable, impactful, and useful.

Research Question/Aims

Aim

This study will:

- Test and finalise the processes for undertaking a definitive, fully powered cluster RCT which compares the effectiveness and cost-effectiveness of a nature-based intervention with a wait list control group for adults with mild-to-moderate depression and/or anxiety. During the main study, the intervention group will receive nature-based activities in addition to usual care.

Objectives

This pilot RCT and process evaluation (GREENGAGE) will provide information to design a definitive cluster RCT of nature-based activities in a group intervention format. As such it will:

- Measure recruitment rates at each site per month and inform optimisation of our models of recruitment.
- Measure rates of adherence during the intervention (percentage of participants attending at least four of the six (67%) nature-based activity sessions).
- Measure rates of loss to follow-up and data completeness
- Produce evidence to inform decisions regarding the primary outcome and primary endpoint for the definitive RCT.
- Estimate standard deviations of outcome measure to inform sample size calculation for the definitive RCT.
- Investigate the acceptability of being randomised to the intervention or wait list control groups to participants, and reasons for attrition.
- Explore the acceptability of proposed clinical and health economic measures to participants.

- Explore participants' experiences of the wider trial processes to refine these for the definitive trial.
- Explore the experiences of the nature-based providers of taking part in the pilot RCT.
- Understand the factors that support or challenge nature-based providers' ability to deliver the intervention in accordance with Handbook mechanisms.
- Develop a bid for a definitive RCT to be submitted to an appropriate funder (e.g. NIHR/MRC).
- Cost the intervention.
- Explore whether travel costs and/or residence in an area with relatively high social deprivation are correlated to participants' attendance
- Pilot data collection methods/instruments for resource use, health-related quality of life and well-being

Public and Patient Involvement/Engagement

Previous PPI/E

The Health and Environment Public Engagement network (HEPE) is a standing network of citizens from across the Southwest Peninsula, including mental health (MH) service users and people involved in community sector service delivery, who work with researchers at the University of Exeter's European Centre for Environment and Human Health (where the project lead is based). HEPE has a long-standing interest in the potential of nature-based activities to support mental ill health and have advised us during the feasibility study, and the drafting of this current, proposal.

Within the previous feasibility work, consultation with two PPI/E groups convened for the study was undertaken in London and Cornwall. Members of these groups who expressed an interest in continuing their involvement in this phase have been invited to do so.

For the feasibility phase, we created vignettes using fictional personae to represent a range of characteristics and experiences, and to facilitate discussion of practical, personal, health and social challenges that people might have in a way that could help externalised issues which might be personally sensitive to participants. These personae were used to facilitate discussion and explore key issues related to outcomes, recruitment, randomisation, and keeping participants engaged. These discussions emphasised:

- That important outcomes might also include improvements in mood, sleep patterns, energy levels, self-confidence and personal resilience, and reduced loneliness/social isolation. Given we are trying to balance information gathered with participant burden, we have selected to also measure loneliness as this is connected with poor mental health and is a common reason for social prescribing referral.
- The importance of multiple routes of recruitment to a research study, particularly outside the GP/primary care context, and with the aim of ensuring diversity of populations. Suggestions included newsletters and social media networks linked to organisations providing nature-based activities, other community networks, local Facebook groups, libraries and GP surgeries. It was also suggested that Patient

Participation Groups in research active GP practices could support local recruitment. As a result, we are planning multiple routes for recruitment.

- The willingness of participants to accept randomisation was seen as depending on a number of factors including: the level of trust between the potential participant and their GP/the research team; their level of distress or the specific needs they were experiencing; and what other support/treatment they were being offered. The wait list control study design was seen as significantly more attractive than being randomised to nature-based activities or usual care, but the wait for this should not be too long.
- Good communication and the building of trust, going beyond the completion of study questionnaires, were seen as the most important ways to keep people engaged, particularly those allocated to a control group in a randomised study. Providing them with information and feedback, making them feel that their contribution counts was seen as important. Newsletters and social media about the project were seen as potential ways of keeping in touch. Sharing people's stories about taking part could also be encouraging for those on the waiting list. It was also recognised that continuing support service providers may be needed to enable some patients to remain engaged. If their mental health or social circumstances deteriorated, or practical issues like transport or caring responsibilities became more pressing, they may need to drop out of the study. We are planning to have a project website and newsletter for all participants in both intervention and control groups to try and ensure that they feel involved.

Planned PPI/E

Katie Gibbs will coordinate public engagement work with support from the wider team. This builds on previous work and will take the form of two main streams:

- A public partner group drawn from HEPE and interested public partners who were involved in the feasibility study will be consulted throughout the project. Katie will host structured workshops to obtain feedback on key trial materials, including the project website and sign-up process and associated communication tools. Katie will also provide feedback on the results of the pilot and planning for next steps.
- Two lay members of the project steering group.

Equality, Diversity and Inclusion Assessment

Inclusion of underserved groups

The project is targeted towards people with mild-to-moderate depression and anxiety. We know that some groups may be more at risk of mental ill health, including those from the poorest households, those with long term physical health conditions, people from African-Caribbean communities, and those from LGBTQIA+ communities. We will also consider place-based inequalities. We will be offering nature-based interventions in three localities in the South West: Wildfowl and Wetlands Trust near Bridgwater Somerset, Eden close to St Austell Cornwall, and the Sensory Trust in Cornwall. Many coastal communities experience high levels of poverty related distress and suffer from health and wealth inequalities, which can be "hidden" in regional statistics (CMO, 2020). Furthermore, despite apparent availability of green and blue spaces, those from socially deprived areas are less likely to access these. Rural communities may also suffer from access issues and have high levels of need. For example, Bridgwater in

Somerset (close to the Wildfowl and Wetlands Trust site) contains the most deprived wards in Somerset, with nearly two-thirds of households experiencing deprivation according to at least one of the four metrics in North Bridgwater (ONS census data 2021).

We will work closely with our nature-based provider partners to identify suitable local community and social media groups through which our pilot RCT can be advertised to try and ensure that a diverse participant population is recruited. Use of inclusive language and images will be supported. The process evaluation will assess how well these strategies work. We will also work closely with nature-based providers to understand how activities and access may affect accessibility for people with health conditions or impairments, encourage adaptations where feasible, and provide clear guidance to potential participants in recruitment material where adaptations may not be possible

Those with serious or complex mental ill-health will not be able to participate due to the type of support available from the nature-based providers. We will use an online screening tool (also used in the feasibility study, IRAS317076) for interested people and those scoring high on the PHQ9 or GAD7 will not be able to participate in the RCT. Instead, they will be directed to appropriate alternative sources of support. If people are unable to navigate the online mood screener or need help understanding and answering the questions, they will be able to email, text or call a member of the research team who will help them to work through the screener questions. The contact details will be highlighted on the screening pages. This support will be available throughout the duration of the recruitment process but primarily during working hours.

Participants will need a good understanding of English to take part in the trial, as all intervention instructions -including safety guidance related to specific activities and tool use - will be delivered in English by the nature-based providers on the day. This requirement will be clearly outlined in the eligibility guidelines. Given the limited capacity of these small VCSE organisations, staff are unable to provide multilingual support or accommodate other languages. Additionally, introducing non-English speakers to a group environment where communication barriers exist could lead to discomfort or feelings of isolation, potentially causing harm. This criterion is not intended to exclude non-English speakers but rather to ensure a safe and ethically sound trial within the current practical constraints.

Trial Design

GREENGAGE is an external parallel arm, pilot RCT with an embedded qualitative process evaluation. This will compare a nature-based intervention (plus usual care – including medication, talking therapy, other social prescription activities) with a waitlist control arm receiving usual care, using individual 1:1 randomised allocation within each of the 3 locations. The results will inform a definitive fully powered trial.

Trial Setting

This is a multicentre trial, with nature-based activities being offered in three locations in the South West of England:

1. Wildfowl and Wetlands Trust (WWT) near Bridgwater, Somerset.

2. Eden Project, near St Austell, Cornwall.
3. Sensory Trust, near Falmouth, Cornwall.

Site-Specific Requirements
Each site is responsible for organising and delivering nature-based activities in accordance with the trial protocol and handbook. These activities will include guided nature walks, conservation tasks, pond dipping, and other therapeutic outdoor activities. Sites must ensure:

- Availability of suitable outdoor spaces for the intervention.
- Accessibility for participants with mild-to-moderate physical limitations.
- Trained facilitators to deliver activities safely and effectively.

Types of Sites and Their Roles

- **Participant Identification Centres (PICs):** General practitioners (GPs), link workers, social media platforms, and community flyers will function as PIC sites. These sources will facilitate participant identification by providing study information and directing potential participants to the project website. No research procedures, including consent or data collection, will take place at these sites. A list of the PIC sites, including contact details of GP's, is maintained by the trial management team and available upon request.
- **Recruiting Sites**: The project website serves as the sole recruiting site for this study. All potential participants will be directed to the website, where they will access the Participant Information Sheet, review eligibility criteria, and provide online consent before completing a screening tool. Those who meet the eligibility criteria will then be enrolled into the study through the website.
- **Intervention Delivery Sites**: The three nature-based providers listed above will deliver weekly group activities for six consecutive weeks. They will document relevant processes and pathways and engage in a focus group discussion to describe their experiences of being involved in the trial.

Eligibility Criteria for Intervention Delivery Sites and Facilitators

- **Sites**: Intervention sites must be located within the designated geographical areas and possess the necessary facilities to support group nature-based activities in an accessible and safe environment.
- **Facilitators**: Facilitators must have experience in leading nature-based activities and be trained in participant safety, inclusivity, and first aid. Additionally, they will complete an online training webinar, delivered by the research team, to ensure they understand the study's purpose, as well as their roles and responsibilities within it.

Participant Population
Participants will be adults aged 18+ with mild-to-moderate depression and/or anxiety. These individuals will be identified through primary care settings, such as GP practices, and via community outreach and social media advertisements. Given the prevalence of anxiety and

depression, participants are anticipated to come from both rural and semi-urban areas, including underserved and socioeconomically disadvantaged populations.

Usual Care Pathways
Participants will typically receive usual care through GPs or mental health services, including medication, talking therapies, or other forms of social prescribing. The trial integrates with these pathways to recruit participants and complement existing support mechanisms. This trial setting reflects the practical considerations of delivering community-based interventions while ensuring access for diverse participant groups.

Participant Eligibility Criteria

Inclusion criteria

- People aged 18 years or over.
- People with mild-to-moderate depression or anxiety, defined by scores of 10 to 19 on PHQ-9 and/or 5-14 on GAD-7. With that, participants can have no/low depression and mild to moderate anxiety, mild to moderate depression and no/low anxiety, or both mild to moderate depression and mild to moderate anxiety.
- Ability to give informed consent to written information sheets and consent forms.
- Participants may be on any current treatment for mild-to-moderate depression and/or anxiety, or none.

Exclusion criteria

- People with severe depression and and/or anxiety (as defined by scores of 20 or more on the PHQ-9 and/or 15 or more on GAD-7)
- People unable to understand written and verbal instructions in English
- Those with serious physical impairment that would prevent participation in nature-based activities (such as walking, gardening, pond dipping)
- Severe and enduring mental disorders
- Actively suicidal or psychotic (as assessed by the mood screener – see Appendix 1).

Recruitment and Participant Identification

We aim to recruit 84 participants (42 in each arm) across three nature-based providers: the Wildfowl and Wetlands Trust, the Eden Project, and the Sensory Trust. These participants will be adults (≥18 years old) with mild-to-moderate depression and/or anxiety, defined by scores of 10-19 on Patient Health Questionnaire (PHQ-9) and/or 5-14 on Generalised Anxiety Disorder assessment (GAD-7).

We will use multiple approaches to reflect the plurality of typical access routes, maximise participant numbers and aim to recruit a diverse population into the study. We will recruit via:

- GP practices in each area
- local link workers/ community connectors
- social media (e.g. local Facebook advertisements, nature-based provider accounts and pages)
- flyers in local community venues, MH support groups

In our single-arm feasibility study, we used both GPs and direct recruitment through social media (local Facebook adverts, nature-based provider routes). While initially recruitment through GPs was slow, reflecting winter workload and staff challenges, we recruited 55% of participants through this route in the feasibility study. Each of the three sites will have three local GPs to support recruitment.

GPs and link workers will receive initial information about the research project through an online seminar. They will identify potential participants and direct them to our project website - https://greengage-research.org - to learn more about the study and sign-up if interested. Those recruited via social media or flyers in local community venues will also be directed to our project website.

The GREENGAGE project website will contain further information about the research, detailing our team, the purpose of the trial, our nature-based provider partners, and what to expect from their participation. The project website will also specify the eligibility criteria and will contain the full participant information sheet in addition to the summary version. Interested users will be prompted to provide consent and will complete the screening questionnaires (see Appendix 1), to ensure that they meet the inclusion criteria. Potential participants will be provided with a mobile telephone number to contact a member of the research team (Katie Gibbs) if they have further questions about the study or need support completing the questionnaires during working hours.

If potential participants do not meet the criteria and have more serious/complex mental ill health, they will be notified immediately, and the online screening tool will direct people to a range of alternative support appropriate to the level of need (see Appendix 1). This approach was used successfully previously in our feasibility study.

Consent

Potential participants will receive a detailed consent form outlining the purpose of the study, the nature of their participation, any optional components, and how their data will be collected, stored, and used. The form will also clarify participants' rights, including their ability to withdraw at any stage without consequence. Once participants provide informed consent online, they will receive a secure link to an online tool for collecting demographic information and outcome measures. Participants will have the opportunity to ask any questions before consenting to ensure they fully understand their involvement in the study. To facilitate this, a dedicated phone line to researcher KG will be advertised on the form.

Once the baseline data have been collected, participants will be randomised to either the nature-based activity course (intervention) or the wait list control, and informed by email which trial arm they are in. At this point their contact details will also be shared with the appropriate nature-based provider so that they can introduce themselves and arrange an induction visit and to receive details of the activities that they will be invited to take part in. A paper copy of the consent form will also be available to participants at their induction session with the nature-based providers so that they have a paper copy to refer to if wanted. The induction session will allow participants to see where the course will take place, meet staff, and ask any questions they may have. It will also be an opportunity for the provider to establish whether any additional equipment (wellies, waterproofs etc.) or adjustments are needed and assess any other specific needs.

Randomisation and Blinding/Allocation Concealment

The randomisation process will be set up and tested by the trial statistician. Participants will be randomly allocated (using computer generated random numbers) to the intervention or control group, in a 1:1 ratio stratified by location. The aim is to recruit 28 participants at each of the three locations. Within each location, participants will be randomised in two batches of 14, with seven participants allocated to each trial arm per batch. The seven participants in the intervention arm of a given batch will form the group within which they undertake the intervention. As part of this pilot RCT, one key objective is to assess the speed of recruitment. The maximum time we are willing to wait to recruit 14 participants per batch will be reviewed and discussed in team meetings. Currently, it has been decided that a batch will proceed with no fewer than twelve participants (assuming two could drop out, leaving four in an intervention group). However, the specific time frame for reaching this minimum threshold has yet to be determined.

For each batch, the trial manager will provide the statistician with a list of unique, non-identifying participant numbers to maintain allocation concealment. The statistician will then match these numbers to the pre-generated allocation sequence and relay the assigned allocations back to the trial manager. The trial statistician and health economist will remain formally blinded to group allocation until the analysis begins.

Other members of the research team will not be formally blinded, as they may need to access participant data or may inadvertently learn group allocations. For example, green providers may report participant engagement using names (since they lack access to participant identifiers), such as noting if a participant spends intervention sessions on their phone rather than engaging in activities. Additionally, if participants contact the research team to enquire about their group allocation, their names will be recognised alongside their assigned group.

To maintain confidentiality, names, contact details, and participant identifiers will be stored separately and held by the trial manager. Access to these details will be granted only when necessary, such as in cases where a participant poses a risk to themselves or others and needs to be withdrawn from the trial.

Data collection

This pilot RCT will collect both quantitative data and qualitative process evaluation data to inform design considerations for a future full-scale trial.

Quantitative Data

Quantitative data collected from those in the intervention and control groups include measures of mental health and wellbeing (ONS4; sWEMWBS, GAD-7; PHQ-9) and loneliness (UCLA Three-item Loneliness Scale plus an ONS recommended measure). In addition, we will collect data on health service use to inform the health economics evaluation. Outcome measures will be collected at T0 (baseline), T1 (6 weeks after the intervention commences – around 8 weeks post-randomisation) and T2 (post-intervention - around 14 weeks post-randomisation). Full data collection tools are shown in the appendix.

ONS4

The ONS4 Personal Wellbeing Scale is a set of four questions developed by the UK Office for National Statistics (ONS) to measure subjective personal wellbeing. It assesses life satisfaction, feelings that life is worthwhile, and happiness, in addition to anxiety. Each of the four questions in the ONS4 Personal Wellbeing Scale is rated on an 11-point 0–10 scale, where 0 is "not at all" and 10 is "completely." There is no total or combined score; instead, each question is analysed separately to assess different aspects of personal wellbeing. For life satisfaction, worthwhile and happiness, higher scores indicate higher levels of personal wellbeing in these areas. In contrast, higher scores on the anxiety question indicate higher levels of anxiety, which can negatively impact upon wellbeing. The questions are shown in Table 1 below and their respective personal wellbeing thresholds in Table 2.

Table 1: ONS4 measures of personal wellbeing

Measure	Question
Life Satisfaction	Overall, how satisfied are you with your life nowadays?
Worthwhile	Overall, to what extent do you feel that the things you do in your life are worthwhile?
Happiness	Overall, how happy did you feel yesterday?
Anxiety	On a scale where 0 is "not at all anxious" and 10 is "completely anxious", overall, how anxious did you feel yesterday?

Source: Office for National Statistics

Table 2: ONS4 Personal wellbeing thresholds

Life satisfaction, worthwhile and happiness scores		Anxiety scores	
Response on an 11-point scale	**Label**	**Response on an 11-point scale**	**Label**
0 to 4	Low	0 to 1	Very low
5 to 6	Medium	2 to 3	Low
7 to 8	High	4 to 5	Medium
9 to 10	Very high	6 to 10	High

Source: Office for National Statistics

sWEMWBS

We have obtained the necessary license to use the short Warwick-Edinburgh Mental Wellbeing Scale (sWEMWBS) for this study. The sWEMWBS consists of seven items designed to assess mental wellbeing. Each of the seven statements is rated on a 5-point Likert scale, ranging from 1 (none of the time) to 5 (all of the time). The total score is calculated by summing the individual item scores, resulting in a possible range of 7 to 35, with higher scores indicating better wellbeing (see Table 3).**Error! Reference source not found.** The population mean for the measure is 23.6 (CORQ, Warwick 2011). At the individual level, a 'minimal detectable change' is defined as 1 or 3 points, depending on the analytical method used. This refers to the threshold

at which a change in a person's sWEMWBS score is considered meaningful rather than due to random variation or measurement error.

Table 3: sWEMWBS Items

Questions	Response set
I've been feeling optimistic about the future	1 None of the time 2 Rarely 3 Some of the time 4 Often 5 All of the time
I've been feeling useful	
I've been feeling relaxed	
I've been dealing with problems well	
I've been thinking clearly	
I've been feeling close to other people	
I've been able to make up my own mind about things	

GAD-7

The Generalised Anxiety Score (GAD-7) asks seven questions, with a Likert scale format (0 to 3), to assess overall levels of anxiety over the previous two weeks and how often specific aspects have been experienced (Table **Error! Reference source not found.**4). The total score is the sum of the individual item scores, with a possible range of 0 to 21. Higher scores indicate greater anxiety: 0 to 4 – minimal anxiety; 5 to 9 – mild anxiety; 10 to 14 – moderate anxiety; 15 to 21 – severe anxiety. If one of the seven items is missing, then the total score is calculated by multiplying the mean of the six non-missing items by 7 and dividing by 6. If two or more items are missing, then the total score is not calculated.

Table 4: GAD-7 scale

Over the last two weeks, how often have you been bothered by the following problems?	Response set
1. Feeling nervous, anxious, or on edge	0 Not at all 1 Several Days 2 More than half the days 3 Nearly every day
2. Not being able to stop or control worrying	
3. Worrying too much about different things	
4. Trouble relaxing	
5. Being so restless that it is hard to sit still	
6. Becoming easily annoyed or irritable	
7. Feeling afraid, as if something awful might happen	

PHQ-9

The Patient health Questionnaire (PHQ-9) consists of nine questions, each rated on a Likert scale from 0 to 3, to evaluate the frequency of depressive symptoms over the previous two weeks (see Table 5).**Error! Reference source not found.** The total score is calculated by summing the individual item scores, resulting in a possible range of 0 to 27, with higher scores indicating greater depression severity. The threshold for scores on the PHQ-9 are as follows: 0 to 4 – no depression; 5 to 9 – mild depression; 10 to 14 – moderate depression; 15 to 19 – moderately severe; and 20 to 27 – severe depression. If one item is missing, the total score is estimated by calculating the mean of the eight completed items, multiplying by 9, and dividing by 8. However, if two or more items are missing, the total score cannot be calculated.

Table 55: PHQ-9 scale

Over the last two weeks, how often have you been bothered by the following problems?	Response set
1. Little interest or pleasure in doing things	0 Not at all 1 Several Days 2 More than half the days 3 Nearly every day
2. Feeling down, depressed or hopeless	
3. Trouble falling asleep, staying asleep, or sleeping too much	
4. Feeling tired or having little energy	
5. Poor appetite or overeating	
6. Feeling bad about yourself - or that you're a failure or have let yourself or your family down	
7. Trouble concentrating on things, such as reading the newspaper or watching television	
8. Moving or speaking so slowly that other people could have noticed. Or, the opposite - being so fidgety or restless that you have been moving around a lot more than usual	
9. Thoughts that you would be better off dead or of hurting yourself in some way	

Loneliness

The ONS recommends four items to measure loneliness; three indirect questions that comprise the UCLA Three-Item Loneliness scale (which are summed to give an overall score) and a separate direct question about how often the respondent feels lonely (Table 6).

The UCLA Three-Item Loneliness Scale consists of three questions assessing different aspects of social isolation and perceived loneliness. Each item is scored on a three-point Likert scale, with responses ranging from "Hardly ever or never" (1) to "Often" (3). The total score is obtained by summing the responses to the three items, with higher scores indicating greater loneliness.

The single-item direct measure, asking "How often do you feel lonely?". This question is rated on a five-point scale, ranging from "Never" (1) to "Often/Always" (5), with higher scores indicating greater loneliness.

The ONS does not specify cut-off scores to categorise loneliness levels. Instead, scores are typically analysed as continuous variables, where lower scores suggest fewer feelings of loneliness, and higher scores indicate greater loneliness.

Table 6: Loneliness Measures

Measures	Items	Response categories
The UCLA Three-Item Loneliness scale	1. How often do you feel that you lack companionship?	1 Hardly ever or never 2 Some of the time 3 Often
	2. How often do you feel left out?	
	3. How often do you feel isolated from others?	

The direct measure of loneliness	How often do you feel lonely?	5 Often/always, 4 Some of the time, 3 Occasionally, 2 Hardly ever, 1 Never

Source: Office for National Statistics (https://www.ons.gov.uk/peoplepopulationandcommunity/wellbeing/methodologies/measuringlonelinessguidanceforuseofthenationalindicatorsonsurveys)

Decliner Data

Decliner questionnaires will be sent to those who are eligible to participate but choose not to and drop out. The questionnaire will be sent to those who do not complete the 6 sessions (see appendix).

Cost Data

Cost data will be collected from the nature-based partners to understand the full cost of delivering the intervention, and a health service use questionnaire will be completed by participants to establish usual care and assess the impact on usual care of the nature-based intervention.

Qualitative Data

The qualitative component of this pilot RCT will be a process evaluation designed to assess the acceptability of the intervention and trial procedures. This evaluation will provide valuable insights into participant experiences of the trial processes and the practical implementation of the intervention. Findings will inform refinements to the study design and delivery ahead of a future definitive RCT, ensuring that it is both methodologically robust and practically viable.

To achieve this, qualitative data will be collected through:

1. **Participant Focus Groups (Intervention Group)**

   One focus group discussion will be conducted at each intervention site, with participants purposively sampled to ensure diversity in personal characteristics (e.g., age, gender, work status). Thus, there will be three participant focus groups in total. These discussions will explore participants' experiences of the intervention, elucidating potential barriers to engagement and suggestions for improvement. Additionally, participants will reflect on the research process itself, including recruitment, consent, data collection, and any perceived burden of participation. Understanding these factors will help refine both the intervention and trial procedures to enhance participant retention and engagement in the future definitive RCT.

2. **Waitlist Control Group Focus Group**

   A separate focus group will be conducted with participants allocated to the waitlist control group to explore their experiences of delayed participation. This will assess

whether the waitlist control design influences participant motivation, engagement, or expectations of the intervention. Additionally, it will explore whether participants allocated to the waitlist control group engaged in any nature-based activities prior to their engagement in the intervention. Insights from this group will help determine whether a waitlist control remains a suitable comparator for the full RCT or if modifications are needed to improve adherence and retention.

3. **Nature-Based Provider Focus Group**

A focus group will be conducted with facilitators and providers delivering the intervention to explore their experiences of engaging with the research project. Discussions will identify factors that support or challenge their involvement, including logistical, practical, and resource-related considerations. This will ensure that delivery of the intervention is feasible and sustainable for providers, helping to refine intervention delivery before scaling up. This will be complemented by ongoing provider engagement meetings and record keeping. Regular contact meetings with nature-based providers will be held throughout the trial to maintain engagement, identify ongoing challenges, and document potential solutions in real-time. These meetings will help address emerging implementation issues, ensuring that facilitators feel supported, and that intervention fidelity is maintained. Capturing provider perspectives on an ongoing basis will provide valuable considerations for the scalability of the intervention model for the future RCT.

Assessment Processes

Table 7: Quantitative data collection

Tool	Purpose	How*	When
Decliner survey	To understand non-participation	Self-reported online survey – including free text space	At recruitment
Screening PHQ9 and GAD7	To ensure participants meet inclusion criteria	Self-reported online screening tool with associated support signposting	Prior to consent
Participant characteristics	To describe study demographics & any current MH treatment	Self-report online questionnaires	After consent, baseline questionnaire T0
Mental health: PHQ9 GAD7	Clinical MH outcome measures	Self-report online questionnaires	After consent baseline questionnaire (T0), post-intervention follow-up (T1), follow-up (T2)
Wellbeing: ONS4 SWEMWEBS	Clinical wellbeing measures	Self-report online questionnaires	After consent baseline questionnaire T0, Post randomisation T1, follow up T2

Loneliness: UCLA (3 item scale) Direct questions	To describe level of loneliness	Self-report online questionnaire	After consent baseline questionnaire T0, Post randomisation T1, follow up T2
Health economics	Healthcare use questionnaire	Self-report online questionnaires	After consent baseline questionnaire T0, Post randomisation T1, follow up T2
Participation survey	Understanding processes and issues, extent of nature-based activity by control group during their wait period, and including group dynamics that may be hard to establish in the focus group	Self-reported online survey – including free text space	Post-intervention (T1)
Drop Out/Withdrawer Survey	Understanding reasons for withdrawing from the research, relevant to both active intervention groups and waitlist controls	Self-reported online survey – including free text space	Any time post-randomisation

* For online questionnaires, all participants will be offered the option of research support over the phone or zoom/teams call to support completion where required.

Table 8: Qualitative data collection

Purpose	**Who**	**How**	**When**
To understand how planned activities are mapped to handbook mechanisms	Nature-based providers and participants	Research observation	During the intervention
To understand participants' experiences of trial processes (including randomisation, questionnaires etc)	Participations in the intervention arm	Focus group discussions (one at each of the three sites)	Post-intervention
To understand participants' experiences of trial processes (including randomisation,	Participations in the control arm	Focus group discussions	Prior to their participation in the wait list intervention.

communication, wait list control, type of nature-based activity during their wait period etc.)			
To understand the experience of trial participation (support, challenges, payments etc)	Nature-based providers	Focus group discussions	After the wait list intervention has taken place.

Trial Procedures

Participation in the trial will involve:

- Written consent
- Completion of the screening tool
- Completion of the baseline questionnaires (T0) for both the intervention and control arms:
    - Participant characteristics
    - Mental health and wellbeing measures
    - Health service use questionnaire
- Random allocation to either the intervention arm (nature-based activities) or the control arm (usual care, wait list)
- Those allocated to the intervention arm 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.
- Completion of questionnaires after the intervention at T1 (8 weeks post-randomisation) and T2 (14 weeks post-randomisation) arm:
    - Mental health and wellbeing measures
    - Loneliness measure
    - Health service use questionnaire
- Participation in a focus group discussion about their experience of the processes and delivery of pilot trial (optional) following T2
- Completion of T1 and T2 questionnaires for the waitlist control group:
    - Mental health and wellbeing measures
    - Loneliness measure
    - Health service use questionnaire
- Those allocated to the control arm will be offered the opportunity to take part in a 6-week programme of nature-based activities after the follow-up period (T2).

The Intervention

The intervention to be delivered as part of this study is informed by previous research by the team (MRC PHIND MR/S002286/1). Realist review methods, stakeholder consultation and built on the MRC guidance for developing complex interventions, was used to develop the *Handbook*

for Nature-on-Prescription (Fullam et al, 2021). In the handbook, we detail key active mechanisms, common to many types of nature-based activities, though which benefits may come about. The handbook details strategies to optimise delivery of nature-based interventions through incorporation of activities that activate these pathways. Key mechanisms are:

- Group-based participation. When positive and meaningful psychological connections are established between group members, the content of health interventions may be enhanced (Tarrant et al, 2016). Groups can reduce loneliness (a common reason for SP referrals), build self-esteem, reduce worry and rumination and reduce a sense of despair and hopelessness.
- Caring for things. People can find solace, and develop self-esteem, in caring for plants, nature, and/or animals and develop a sense of reciprocal benefit between themselves and nature (Sempik et al, 2010). They may also care for others in the group and for themselves through this process.
- Having fun and enjoyment, is an important component of wellbeing, helping to contribute to a worthwhile and satisfied life (Haworth, 2016). It is also linked to completion and adherence with health-related interventions (Herens et al, 2016).
- Personal growth. While this may be through formal therapeutic approaches, such as CBT, or meditation skills, such as mindfulness, even without formal approaches, participants can develop knowledge or skills and experience a range of achievements.
- Making a difference. Some forms of nature-based activities involve tangible, and potentially appreciated, contributions to the community (e.g. through improving the environment) This can contribute to mental health, social function, and wellbeing (Lovell et al, 2015).
- Creating. Active processes of 'making' may benefit wellbeing (Thomlinson et al 2018). Nature-based creative activities, including gardening, have been linked to mental health through refuge from stress, and self-development (Genter, 2015).
- Physical activity. Exercise and physical activity have been shown to support physical and mental health (Cooney et al, 2013; Penedo et al, 2005) and exercise in outdoor natural environments is more beneficial, in terms of self-reported mental wellbeing, than that taking place indoors (Thompson Coon et al, 2011).
- Being outside. Participants in nature-based interventions describe the outdoor environments as simple, peaceful, and, crucially, 'away' or 'other' to their usual environment, offering fresh air, a change of scene and a sense of space (Burls et al, 2007; Maund et al, 2019).
- Developing a relationship with nature. This mechanism may operate through counteracting stress and increasing the ability to focus and concentrate (supporting Attention Restoration Theory (Ohly et al, 2016)). People may also develop a symbolic association with natural cycles of dormancy and growth, regeneration and regrowth, which they find helpful in understanding their own condition (Garside et al, 2021).

The programme of nature-based activities delivered by each partner organisation will be mapped to these intervention mechanisms to ensure anticipated delivery fidelity. It is expected that all sessions will involve two key mechanisms – being outside and being in a group. In addition, over the course of the programme, the activities will involve at least 80% of the

mechanisms. Researchers will attend at least one session per provider to observe and log how the activities are carried out in practice (fidelity). In addition, all participants will be asked to attend an intervention site induction visit prior to the start of the intervention so that they know how to get there, be introduced to course leaders and orientate themselves in the site and its activities. If participants do not have appropriate waterproof clothing and footwear, this will be provided by the site.

Staff will be experienced in delivering nature-based activities and will have experience and/or training in mental health first aid. In addition, participating organisations have appropriate safeguarding, risk assessment, insurance, data management systems (GDPR compliant) policies as a prerequisite to being a study partner. Nature-based activity providers will be required to log any adverse events such as injuries during the delivered course.

Control Arm

The control arm will continue to receive usual care. To maintain engagement, they will receive a monthly newsletter via email, accessible through our project website. This newsletter will provide updates on the study's progress, recruitment, activities, and related research, helping participants feel connected to the project. For those who prefer a physical copy, a hard copy can be mailed upon request.

At the end of the study, following the collection of outcome measures at T2, they will be offered the opportunity to participate in nature-based activities at the partner sites. Questionnaires and the focus group (see Table 7 and Table 8) will explore the type and nature of any nature-based activity undertaken by the control arm during the waiting period to establish the potential for contamination.

Nature-based Providers

Through learning from the feasibility stage, we better understand the challenges of provider participation. Initial workshops led by the research team will be used to support the groups to map their planned activities to the handbook mechanisms, ensure appropriate staff training and staff are in place, and provide details on the research being undertaken. Capacity issues mean that the providers may not be able to deliver more than one course at a time, and that there may be staff turnover, requiring additional input from the research team to ensure new members understand the expectations of the research project. We have allowed eight months for the providers to run up to three six-week courses with approximately 27 participants in series. The viability of this will be assessed in order to inform the full trial in the future.

The meaningful and committed involvement of nature-based providers throughout the project represents significant investment of time and can affect capacity for their day-to-day activities. Therefore, they will be supported by an initial engagement payment which will enable them to participate in training, delivery refinement workshops, administration associated with recruitment and so on.

Main Objectives

Primary objective

- Establishing recruitment (percentage of those screening who participate) and retention rates of participants in intervention and control arms.

Secondary objectives

- Intervention arm -attendance at >=67% of sessions (4/6 of the weekly sessions, or two-thirds of the intervention)
- Completeness of key outcome measures (PHQ9, GAD7, SWEMWEBS, ONS4, Three-Item Loneliness Scale, health service use questionnaire) at each time-point.
- Estimate the potential effectiveness of the intervention on the outcome measures
- Estimate standard deviations for continuous outcomes
- Intervention costs
- Participant health service use.

Data Management

Quantitative Data

Data will be recorded on the number of participants that are screened for participation and recruited to the pilot trial, further to their attendance of intervention participants at their NBSP intervention course, retention through the trial, and completion of the questionnaire data. Data on participant characteristics (age, gender, education level and postcode) will be collected at baseline. In addition, we will administer the five mental health and wellbeing measures, and the health service use questionnaire (see Appendix).

Qualitative Data

Qualitative data will be generated from a total of three focus groups with active intervention participants (one at each site) plus one focus group with those allocated to the control arm), and one with nature-based providers. Audio data will be recorded and transcribed by a member of the research team (KG). Identifiable participant data will be removed from the transcript to ensure that qualitative insights are anonymised. Audio recordings will be deleted following transcription, and the anonymised text will be uploaded to the team's secure SharePoint.

Sample size and Power Calculations

As this is a pilot trial a formal sample size calculation for evaluating the impact of the intervention on the outcomes is not appropriate. This pilot RCT will enable us to identify the most appropriate primary outcome (through assessing completeness of data provided, score variability, and participant feedback on completing the questionnaire) and sample size for a future full trial. Based on published recommendations for pilot RCT size of 70 (35 per arm) (Tearle et al 2014) we will aim to recruit 84 participants, allowing for 20% drop out up to T1. Each site will aim to run up to three courses, each accommodating 7–10 participants. The minimum required number of participants per course is four. A total of eight groups with at least four participants each provides sufficient sample size to estimate a dropout rate of 15%, with a 95% confidence interval ranging from 8% to 24%.

Planned Data Analysis

Quantitative Data

A full statistical analysis plan will be specified and signed off in advance of data lock.

A CONSORT diagram will be used to describe the participant flow through the trial, with counts and percentages of those recruited and retained in the study (Eldridge et al 2016).

Characteristics related to feasibility of the trial will be reported with 95% confidence intervals, including: the percentage of screened people that are eligible, the percentage of screened people that are recruited, the number of people recruited per location per week, the percentage of participants that provide follow-up data, the percentage of intervention arm participants that attend at least 4 of the 6 nature-based sessions and the percentage of participants that complete each outcome measure. Characteristics of the study participants will be summarised using means and standard deviations (or medians and interquartile ranges) for continuous variables, and numbers and percentages for categorical variables.

As this is a pilot study, estimating intervention effectiveness is not a key objective. However, its potential impact on the mental health and wellbeing outcomes at follow-up will be estimated. Trial arms will be compared using mixed ("multilevel") linear regression models. These models will account for the correlation between the responses of intervention arm participants within the group (cluster). Satterthwaite's degrees of freedom correction will be applied to account for the small number of clusters in the analysis. If there are convergence problems, ordinary linear regression models will be fitted instead. The comparisons will be adjusted for the baseline score of the outcome. Adjusted mean differences between the trial arms and two-sided 95% confidence intervals will be reported; no hypotheses testing will be undertaken. No subgroup analyses will be undertaken.

To calculate intervention costs, the resource used for training and delivering the intervention (preparation, delivery, travel time) will be collected from the trainers and service managers, and nationally applicable unit costs will be applied.

To explore barriers and facilitators to attendance, data collection forms will be designed to allow linkage of attendance data to participants' home postcodes and Index of Multiple Deprivation (IMD) using a participants' unique identifier code. This data linkage will enable us to investigate whether travel costs and/or residence in an area with relative high social deprivation is correlated to participant attendance using the Pearson correlation coefficient. Travel time and mileage from a participant's home postcode to the intervention site will be calculated using Google Maps to incorporate participant travel costs, based on HMRC reimbursement rates (https://www.gov.uk/government/publications/rates-and-allowances-travel-mileage-and-fuel-allowances/travel-mileage-and-fuel-rates-and-allowances).

Data collection methods for primary, secondary and social care resource use, as well as personally incurred expenses (e.g. travel, counselling), informal care/support and workforce participation will also be piloted. These data will be collected from participants using a bespoke resource use questionnaire (www.Dirum.org) and reviewed by PPI members. Responses to the resource use questionnaire will indicate whether participants have difficulties understanding or completing the questions. The potential of the group-based intervention to improve wellbeing during the trial will be measured using ONS4. Additionally, SWEMWBS will be used to calculate

a Mental Well-being Adjusted Life Years (MWALYs) using the preference-based, UK tariff derived from members of the general public (Yiu et al., 2023).

Qualitative Data

As part of the process evaluation, focus group discussions will be conducted with the three target populations to explore their experiences of being involved in the trial and identify perceived barriers and facilitators. These discussions will be led by Katie Gibbs (Research Fellow), with support from a member of the research team. With participants' consent, all focus groups will be audio-recorded and transcribed verbatim. Data management and coding will be facilitated using qualitative data analysis software, such as NVivo, to help organise the data sets and analysis.

Thematic analysis will be conducted following a small-q or codebook approach (Braun & Clarke, 2006, 2012, 2022). The analysis will follow an iterative process, involving multiple readings of the transcripts to ensure familiarity with the data and systematic coding of insights relevant to the research objectives. A second member of the research team will code at least two transcripts before discussing these and refining coding frames to aid interpretation. The codes will then be organised into descriptive themes. Themes will be constructed in relation to the core components of the intervention and process evaluation framework (e.g., capturing implementation fidelity, factors influencing participant engagement and contextual influences). Themes will be clearly defined, with a focus on how they contribute to understanding the intervention's processes and how these might contribute to participant outcomes. The analysis will be discussed with the core research group at regular team meetings to ensure the clarity of existing themes and to offer an opportunity for additional insights and perspectives to be explored. Some themes may be merged, refined, or discarded based on their relevance and coherence. The final thematic structure will provide a rich narrative outlining key findings, offering insights into the feasibility, acceptability, and implementation of the intervention. The results will help refine the intervention and inform the design of a future full-scale trial.

Data collection, entry, coding and checking processes

Quantitative data

Data management, coding, and checking will be carried out by the research team in accordance with legal requirements and the data management and research governance procedures of the University of Exeter. Personal data will be stored only as long as necessary after the study concludes, and with participants' consent, we aim to provide a summary of our findings within six months of the study's completion. Data generated from the study will be securely archived on password-protected University of Exeter servers for 10 years. Due to the small sample size of this pilot RCT, there is a risk that sharing data could compromise participant confidentiality. Additionally, we do not have the resources to facilitate data sharing in a way that ensures anonymity. As a result, we will not be making the dataset publicly available.

Nature-based providers will record participant attendance for each session using a pre-specified data collection tool.

All participant questionnaires will be completed online using formats that are accessible using a smart phone. If participants are unable to complete the online forms, then paper copies can be sent with a stamped addressed envelope for return. These will be collected at three time points – at baseline (T0), after the 6-week intervention (T1) and after a further 6 weeks follow up (T2). These data will be finalised and analysed by the research team, including the statistician and health economist.

Qualitative data

Focus groups will be audio recorded before being transcribed verbatim. The research team will analyse these using NVIVO software. A second member of the research team will also code at least two scripts before discussing these and refining coding frames and understandings. The analysis will also be discussed with the core research group at regular team meetings.

Missing Data

To minimise missing data, we will use online data collection platforms, including Qualtrics and REDCap. Screening responses to the GAD-7 and PHQ-9 (hosted on Qualtrics) will be mandatory, as these measures are essential for determining participant eligibility. However, at T0, T1, and T2, where responses are optional, participants will be prompted to review their answers to ensure they are satisfied with their responses. If a participant chooses not to answer a question, we will respect their preference and allow them to proceed, as we do not wish to compel responses regarding mental ill health. Missing data will be documented in the pilot study write-up to inform the design of the full-scale RCT. All anonymised data will be securely stored on University of Exeter SharePoint servers in compliance with data protection regulations.

Potential Bias

Bias	Description	Risk	Mitigation
Selection bias	Possible underrepresentation of participant groups (e.g. ethnicity, gender, age etc). Maybe due to demographics of local populations, inequities in access to services, perceptions of who nature-based activities are for, recruitment modes,	Medium	Multiple routes of recruitment. Inclusive imagery and language on recruitment tools and websites. Nature-based providers from different localities. Waitlist control group
Observation bias	Inability to blind participations to their allocated study arm – intervention group may score more favourably at follow up.	Medium	Statements on recruitment material that effectiveness evidence is currently lacking.
Attrition bias	Higher withdrawal from control group due to not receiving the nature-based intervention	Medium	Clear description of the trial and randomisation in the information sheets. Offering chance to take part in nature-based activities after a waiting period.

			Communication with the control group throughout the trial period.
Detection bias	Research team influences assessments due to knowing allocation.	Low	Blinding of analysts until detailed data plan finalised.
Contamination	Additional nature-based activities undertaken by the control group.		Focus groups and participation surveys will assess participants engagement with nature outside of the intervention

Data protection and confidentiality

The researchers will comply with the requirements of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 (DPA 2018) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

From the outset of the study, participant contact details will be stored on secure University of Exeter cloud servers and accessed using University devices (laptops/desktops) that are password protected, encrypted and fully up to date with regard to information governance security software. Contact details will only be kept beyond the life of the project if consented to and will be stored in the same way as during the project. With consent, contact details of participants will be shared with the nature-based provider partners so they can contact participants with information about the activities and schedules of the intervention – this data will not be used for any other purposes and partners are aware of the need for confidentiality and data handling requirements. They will be stored separately to the research data, and linked through a unique ID. Only members of the project team and the study sponsor will have access to the data.

Any hard copies will be stored in locked filing cabinets at the University of Exeter, accessible only to the research team. At the end of the study, any hard copies will be scanned and paper copies destroyed as confidential waste. Only anonymised data will be available for sharing providing the participants consent to this.

In any publications, only aggregated quantitative data will be used and qualitative data will be anonymised and any identifying information removed.

The participant focus groups will be recorded and audio files will be uploaded from recorder to computer as soon as possible after interview. The audio files will be transferred to the transcriber via the University of Exeter secure network drive as arranged with the Information Governance team. Once the interviews have been transcribed (by a transcriber whose contract has been approved by the university legal department), transcripts will be checked by members of the research team. Once these have been checked and verified for accuracy audio files will be securely destroyed and transcripts will form the primary data source for analysis. Only the research team will have access to the transcripts. Hard copies will be stored in a locked cabinet in the office of the Chief Investigator and destroyed at the end of the project (only electronic copies will be kept for 10 years). Electronic files will be stored on secure cloud servers that are password protected, encrypted and fully up to date with regard to security

software. Online back-up files will be stored on a secure University server with access to the files controlled by the project Chief Investigator.

Ethical and regulatory considerations

Quantitative data collection will involve the participants answering questions about how they feel and their mental health, including anxiety and depression specific instruments. Sometimes reflection on the issues raised by the data collection tools can cause distress. Participants will be reminded that they don't have to complete the information if they don't want to, with no dis-benefit to themselves. Details of local GP and MH services will be provided online with the questionnaires and in the information sheets.

In the focus groups, participants will be told they can take a break or stop taking part at any time. If people seem to be upset, the researcher moderating the focus group will check in with them, ask if they want to continue, and given the chance to leave the group. They will be followed up a researcher (all groups will have 2 moderators). Moderators will comfort them and reassure them if possible and will have a list of local numbers to supply to the participants if helpful.

In the event that there were concerns around the health or well-being of participants then these would be flagged by the providers, discussed with the participants and the PI contacted if necessary. It will be made clear in the Participant Information Sheet that the researcher has a duty to inform an individual's GP if, during the course of discussions, they become aware of any risk or harm to the participant themselves. Researchers would always discuss this with the participants before doing so, unless the urgency of need makes this impractical.

A list of local mental health support numbers and the Samaritans will be provided with the participant information sheets.

The study is subject to HRA Assessment to obtain ethical approval.

Assessment and management of risk

All activities will take place outdoors, there may be inclement weather, minor injuries related to walking, use of gardening equipment etc. The nature-based providers will log any adverse events and follow their existing policies and procedures for dealing with minor injuries.

Participants will be advised to bring any allergy medication they have with them (in case of, for example hay fever) and will be required to inform the group leader if they have any serious allergies, (for example to bee stings), or health conditions that may be affected by taking part in the activities.

Green partners are experienced practitioners and will abide by their own risk and safety policies during the intervention.

The study may involve the research fellows working on sites away from the University of Exeter. Prior to any visit they will inform the Chief Investigator of the location and schedule in accordance with the University of Exeter lone working policy. A dedicated project phone sim card will be acquired for the project.

Research Ethics Committee (REC) and other Regulatory review and reports

Before the start of the study, ethical review and approval will be sought from the Health Research Authority (HRA) for the assessment of ethical compliance within the NHS and in order to obtain HRA Approval.

Prior to commencement of any research procedures local NHS site confirmation of 'capacity and capability' will be confirmed by any NHS sites and a 'green light' in place from the sponsor.

Project timetable

Milestone	**Date**
Ethics and HRA approval	April 2025
Recruitment and allocation commence	May 2025
Start nature-based intervention delivery	June 2025
End all nature-based intervention delivery	December 2025
All focus groups conducted by	January 2026
Data analysis complete	February 2026
Report write up	March 2026
Close of study	31st March 2026

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