

# Outdoor swimming as a nature-based intervention for depression

<b>Submission date</b> 06/02/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/02/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/03/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Many people say outdoor swimming improves their mental health. There has been some research to suggest it helps people with depression, but not enough to say for certain. This study will help determine if an eight-session outdoor swimming course (plus usual care) is a clinically and cost-effective intervention for depression, compared to usual care alone.

### Who can participate?

People aged 18 years and older who are living with symptoms of depression, who would like to try outdoor swimming.

### What does the study involve?

People interested in the study can find more information on our website ([outside2.co.uk](https://outside2.co.uk)) and they can sign up through the website. Individuals who decide to take part will either have eight 1-hour sessions of outdoor swimming with a small group, as well as their usual care, or have their usual care only. Usual care may include talking therapies and/or antidepressant medications and community activities. The usual care-only group will be offered the swimming course after the study finishes. The outdoor swimming courses will be run by experienced coaches and will build confidence and water safety skills. During the study, participants will fill out questionnaires that ask about their depression, mental health, wellbeing, and use of health care services. Participants will complete them before the study starts, immediately after the swimming course (or usual care) and 6 months later. During the courses, the researchers will ask participants to keep a diary about their experiences and may visit during the course to ask participants about their experiences. Swim coaches will be asked to provide attendance figures and asked to describe the activities that each session included.

### What are the possible benefits and risks of participating?

Possible advantages may include being outside, an improvement in mental health and wellbeing, an improvement in physical health, and some may also find being around people beneficial. The water is cold, some people find this unpleasant whilst many report increased feelings of wellbeing. People with underlying physical health conditions should speak to their GP before participating in outdoor swimming. Participants are welcome to wear a wetsuit if they have one or can borrow one. Participants will be encouraged to get out of the water before they become

cold. Participants will be given information about what to bring with them, how to warm up after swimming and encouraged to bring a hot drink in a flask to have at the end.

The mental health questionnaires used in this study include sensitive questions around suicide, which may be upsetting. The research team will support participants and direct them to further support as needed. The team includes mental health professionals and researchers trained in mental health first aid.

Where is the study run from?

The study is organized and run by Sussex Partnership NHS Foundation Trust (UK). There are swim locations across England. Please see the study website for locations ([outside2.co.uk](https://outside2.co.uk)).

When is the study starting and how long is it expected to run for?

October 2023 to March 2026

Who is funding the study?

National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?

1. Heather Massey (co-lead investigator), [heather.massey@port.ac.uk](mailto:heather.massey@port.ac.uk)

2. Natalie Dailey (clinical trials manager), [n.dailey@bsms.ac.uk](mailto:n.dailey@bsms.ac.uk)

## Contact information

### Type(s)

#### Contact name

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### Type(s)

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#### Contact name

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

328871

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

CPMS 56260, IRAS 328871

## **Study information**

### **Scientific Title**

OUTSIDE 2. Outdoor swimming as a nature-based intervention for depression: a full scale randomised controlled trial

### **Acronym**

OUTSIDE 2

### **Study objectives**

Primary Hypothesis:

Hypothesis 1: The 8-session outdoor swimming course offered in addition to usual care, in comparison with usual care only, will lead to greater reductions in depressive symptom severity from baseline to 12 weeks post-randomisation (post-intervention).

Secondary Hypotheses:

Hypothesis 2: The 8-session outdoor swimming course offered in addition to usual care, in comparison with usual care only, will lead to greater reductions in depressive symptom severity from baseline to 38 weeks post-randomisation (follow-up).

Hypothesis 3: The 8-session outdoor swimming course offered in addition to usual care, in comparison with usual care only, will lead to greater reductions in anxiety symptom severity from baseline to 12 weeks post-randomisation and from baseline to 38 weeks post-randomisation.

Hypothesis 4: The 8-session outdoor swimming course offered in addition to usual care, in comparison with usual care only, will lead to greater improvements in mindfulness from baseline to 12 weeks post-randomisation and from baseline to 38 weeks post-randomisation.

Hypothesis 5: The 8-session outdoor swimming course offered in addition to usual care, in comparison with usual care only, will be cost-effective at 38 weeks post-randomisation.

Hypothesis 6: The swimming courses will be safe, with a low incidence of serious adverse reactions and no lasting negative effects.

An additional aim of the trial is to explore through a qualitative study how participants experience the outdoor swimming course in relation to their experiences of depression. This will help us learn more about the relationship between outdoor swimming and depression. If the primary hypothesis is supported, findings from the qualitative trial will help inform implementation.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 09/01/2024, London Hampstead NHS REC (Health Research Authority, 2 Redman Place, Stratford, E20 1JQ, UK; +44 (0)207 104 8345; hampstead.rec@hra.nhs.uk), ref: 23/LO/0942

### **Study design**

Randomized; Interventional; Design type: Treatment, Complementary Therapy, Complex Intervention, Physical

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

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

Depression

### **Interventions**

Participants will be randomised to either have eight 1-hour sessions of outdoor swimming with a small group as well as their usual care, or to have their usual care only

Participants randomised to the intervention will be invited to an online introductory session lasting 1 hour with the swimming coaches leading the 8-week outdoor swimming course. The course will run for approximately 1 hour a week for 8 weeks. During this course they will also continue with their usual care (medications and therapies). The swim coach will call all participants (irrespective of referral route) before each swim session and will meet participants outside the swim venue. If participants do not answer the phone the swim coach will send a text message as a reminder of the swim session. The focus of these courses would be the safe enjoyment of the water rather than becoming an expert swimmer. All swimmers will be supervised by the course staff (who have basic life support and lifeguard qualifications and have attended courses on mental health first aid and safeguarding for vulnerable adults) and they will only swim if it is safe to do so. It is not possible to offer a completely standardised course as local conditions will dictate what can be achieved in the sessions.

The sessions will include basic swimming skills (Lido only), safety, hazard awareness and risk assessment, and provision of moderate challenges when in the water including floating and in-water-based skills. However, alternative arrangements and session plans will be available for adverse weather conditions that do not allow the swim to take place at the normal time. During the course, participants will be supported to find existing groups or form their own so that they can continue to swim safely after completion of the course.

Usual care may include talking therapies and/or antidepressant medications and community activities. The usual care-only group will be offered the swimming course after the study finishes.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Depression severity is measured using Patient Health Questionnaire (PHQ-9) at baseline, at 12 and 38 weeks post-randomisation

### **Secondary outcome measures**

1. Anxiety symptom severity is measured using Generalised Anxiety Disorder Assessment (GAD-7) at baseline 12 and 38 weeks post-randomisation
2. Mindfulness total and subscale scores measured using the Five Facet Mindfulness Questionnaire (FFMQ-15) at baseline, 12 and 38 weeks post-randomisation
3. Health-related quality of life is measured using EQ-5D 5L and Recovering Quality of Life (ReQoL) at baseline, 12 and 38 weeks post-randomisation
4. Medication, health care resource use and travel to treatments/appointments measured using the Client Service Receipt Inventory-UK at baseline, 12 and 38 weeks post-randomisation
5. The impact of (mental) health on employment in a paid job and on unpaid work, like household chores, quantified using the Institute of Medical Technology Assessment (i-MTA) Productivity Cost Questionnaire (iPCQ) and "ad-hoc" form/logs at baseline, 12 and 38 weeks post-randomisation
6. Relevant set-up and ongoing resources necessary to offer the outdoor swimming courses measured using "ad-hoc" form/logs during the intervention swim courses
7. How participants experience the outdoor swimming course in relation to their experiences of depression, measured using interviews and diaries during the swim courses and interviews following the completion of the study

### **Overall study start date**

02/10/2023

**Completion date**

28/03/2026

## Eligibility

**Key inclusion criteria**

1. Participants give fully informed consent to participate
2. Symptoms of depression, as determined by the PHQ-9 (scores 5 and above) and meeting DSM 5 criteria for Major Depressive Disorder (this will also be assessed using the Mini International Neuropsychiatric Interview [MINI])
3. Self-reported ability to swim a minimum distance in a heated pool for sea (50 m, 2 lengths of a normal swimming pool) and lake (25 m, 1 length of a normal swimming pool) locations, no swimming experience is required for outdoor unheated swimming pools (lidos)
4. Adult aged 18 years or older
5. Able to understand spoken instructions in English or in a language spoken by the swim coaches that are recruited

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

Planned Sample Size: 480; UK Sample Size: 480

**Key exclusion criteria**

1. Risk of suicide (participants deemed a high risk of suicide based on a score of 17 and over from the MINI suicidality module)
2. Evidence of a current psychotic disorder (ascertained from the MINI psychotic disorders module conducted during a phone call with RA and further assessed by the medical team)
3. History of serious cardiac abnormalities determined after medical review and assessment
4. Respiratory conditions triggered by cold such as poorly controlled exercise-induced asthma
5. Cold-water urticaria
6. Participants with a BMI of 17 or under
7. Moderate to severe learning disability
8. History of non-freezing cold injuries, if not mitigated (wearing boots/gloves)

**Date of first enrolment**

23/02/2024

**Date of final enrolment**

31/07/2025

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**Sussex Partnership NHS Foundation Trust**

Trust Hq

Swandean

Arundel Road

Worthing

United Kingdom

BN13 3EP

# Sponsor information

## Organisation

Sussex Partnership NHS Foundation Trust

## Sponsor details

Trust HQ

Swandean

Arundel Road

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England

United Kingdom

BN13 3EP

+44 (0)3003040088

researchgovernance@sussexpartnership.nhs.uk

## Sponsor type

Hospital/treatment centre

## Website

<http://www.sussexpartnership.nhs.uk/>

## ROR

<https://ror.org/05fmrjg27>

# Funder(s)

## Funder type

Government

**Funder Name**

NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR206936

## Results and Publications

**Publication and dissemination plan**

Findings will be written up for submission for open-access publication in high-impact academic journals, including:

1. The trial protocol
2. A paper reporting on main findings in relation to the primary and secondary hypotheses with the intent to publish by approximately 30/05/2027

Findings will be disseminated to participants and service user organisations.

Findings will be presented at service user events and at local, national and international conferences.

**Intention to publish date**

30/05/2027

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

The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date