

Outdoor swimming as a nature-based intervention for depression

Submission date 30/04/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 19/05/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/04/2024	Condition category 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 showing outdoor swimming helps people with depression, but not enough to say for certain. Social prescribing link workers work with GPs to support individuals to take greater control of their own health. They link patients with community-based activities and non-medical support such as gardening, volunteering opportunities or exercise and sports groups. In this study, social prescribing link workers offer an outdoor swimming course to adults with depression to see if it can help them. This study is a small study called a feasibility study. It will help to decide if it is possible to run a larger clinical trial and, if so, how best to design it. The larger clinical trial would show whether outdoor swimming helps improve depression. It will also give information about who and how it might help.

Who can participate?

Adults aged 18 years and over experiencing depression (e.g. feeling down or low in mood) and professionals who work with them

What does the study involve?

People interested in the study can seek information from social prescribing link workers at the study locations. 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 8 weeks later. The researchers will also get feedback from participants, swimming coaches, social prescribing link workers as well as people who declined or dropped out of the study. Their feedback will help to design the full trial. Staff members who participate will be asked to complete questionnaires about their time commitment to the study and asked to provide feedback in a focus group setting.

What are the 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, the team will also direct participants to further support as necessary. The team includes mental health professionals and researchers trained in mental health first aid.

Where is the study run from?

Sussex Partnership NHS Foundation Trust (UK)

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

April 2022 to April 2023

Who is funding the study?

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

Who is the main contact?

Dr Heather Massey

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Study website

<https://sites.google.com/port.ac.uk/outside-website/>

Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309748

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52526, IRAS 309748

Study information

Scientific Title
Outdoor swimming as a nature-based intervention for depression: a feasibility randomised control trial

Acronym
OUTSIDE

Study objectives
1. To assess the feasibility of undertaking a definitive fully-powered randomised control trial (RCT), comparing an introductory outdoor swimming course, offered in addition to usual care,

compared to a group receiving usual care only, in people who have mild to moderate depression.

2. Determine recruitment and retention rates, acceptability of randomisation and measures used to inform the sample size calculation for a definitive fully-powered RCT.
3. Understand the experience of study participants by using focus group discussions, questionnaires and interviews.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval pending, London - Surrey Research Ethics Committee (London - Surrey Nottingham Centre, The Old Chapel, Health Research Authority (HRA), NG1 6FS, UK; +44 (0)207 1048 088; surrey.rec@hra.nhs.uk), ref: 22/LO/0268

Study design

Single-centre feasibility randomized control trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

<https://sites.google.com/port.ac.uk/outside-website/more-information>

Health condition(s) or problem(s) studied

Depression

Interventions

The randomisation procedure will be set up and tested by the trial statistician using <https://www.sealedenvelope.com>™ with 1:1 allocation to either the intervention or control group with stratification by location and random permuted blocks.

This is a feasibility RCT with 1:1 allocation to a swim course and usual care intervention or usual care group. The study includes a qualitative evaluation of participants' experiences of the outdoor swimming intervention with a focus on better understanding barriers and facilitators to engaging in outdoor swimming. Eighty-eight people meeting eligibility criteria for mild to moderate depression are randomly allocated to receive either their usual care along with eight 1-hour sessions of an introductory outdoor swimming course or their usual care. Participants are asked to complete survey measures at baseline, post-intervention or at the same point for the usual care control group and again in follow-up, 8 weeks later. In addition, participants are invited to focus groups to discuss their experiences of the study.

Intervention Type

Mixed

Primary outcome measure

- 1 Recruitment is measured by the number of eligible people consenting to participate in the study by October 2022
2. Retention of participants is measured by the number remaining engaged in the study activities for the duration of the study

Secondary outcome measures

1. Feasibility measures:

- 1.1. Swimming course attendance (intervention arm only) will be measured by totaling the number of sessions each person attends at the end of the study
- 1.2. Completion of questionnaires (in both arms) will be measured by totaling the number of questionnaires completed at baseline, post-intervention or at the equivalent timepoint for the usual care control group and in follow-up
- 1.3. Serious Adverse Events (SAEs) and adverse events will be recorded as they arise during the study
- 1.4. Completeness of data collected in both arms, at each timepoint. This will be measured by the number of questions completed by participants at baseline, or at the equivalent timepoint for the usual care control group and in follow-up.

2. Participant-reported outcomes:

Each measure will be recorded at baseline, post-intervention or at the same timepoint in the usual care control and at follow up:

- 2.1. Depression symptom severity is measured by the Patient Health Questionnaire-9 (PHQ-9)
- 2.2. Anxiety symptom severity is measured by the General Anxiety Disorder-7 (GAD-7)
- 2.3. Wellbeing is measured using the Short form of the Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)
- 2.4. Connectedness to nature is measured using the connectedness to nature scale
- 2.5. Loneliness is measured using the loneliness scale
- 2.6. Self-compassion is measured using the Sussex-Oxford Compassion for Self-Scale (SOCS-S)
- 2.7. Mindfulness is measured using the Five-Facet Mindfulness Questionnaire (FFMQ-15)

3. Health economic outcomes measures to assess health-related quality of life and medical resource use; each measure will be recorded at baseline, post-intervention or at the same timepoint in the usual care control and at follow up:

- 3.1. Health-related quality of life is measured using the EQ-5D-5L
- 3.2. Recovering quality of life is measured by using the ReQoL-10
- 3.3. The type and intensity of usual care, use of other health and social care services, such as GP visits, inpatient/outpatient care, A&E, medication use, travel time and cost to travel to and from all different treatments/appointments attendances, estimated using the Clinical Service Receipt Inventory
- 3.4. Health-related productivity losses measured using the IMTA Productivity Cost Questionnaire

Overall study start date

01/04/2022

Completion date

15/04/2023

Eligibility

Key inclusion criteria

1. Participants give fully informed consent to participate
2. Mild and moderate severity depression, as determined by the PHQ-9 (scores 5 -19)
3. Self-reported ability to swim a minimum distance:
 - 3.1. For sea (50 m, 2 lengths of a normal swimming pool)
 - 3.2. Lake (25 m, 1 length of a normal swimming pool) locations
 - 3.3. No swimming experience required for outdoor unheated swimming pool (lido)
4. Adults aged 18 years or older

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

88

Key exclusion criteria

1. People wishing to participate in a sea location who are not able to swim 50 m (2 lengths) in an indoor or fully heated outdoor pool
2. People wishing to participate in a lake location who are not able to swim 25 m (1 length) in an indoor or fully heated outdoor pool
3. Currently under the care of a secondary mental health NHS service
4. Risk of suicide or recent suicidal intent or attempts or self-harm requiring medical treatment
5. Other mental health problems to a severe degree
6. History of cardiac abnormalities (e.g., ischaemic heart disease/angina and congestive heart failure)
7. Immediate (first degree) relative history of cardiac events (GP consultation will be required for inclusion)
8. Respiratory conditions triggered by cold
9. Coldwater urticaria (a skin reaction to cold that appears within minutes after cold exposure)
10. Non-freezing cold injuries/Raynaud's
11. Not able to speak English to a level that would enable them to understand safety instructions

Date of first enrolment

20/05/2022

Date of final enrolment

04/09/2022

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

ONSIDE advocacy

Williamson House
14 Charles Street
Worcester
United Kingdom
WR1 2AQ

Study participating centre

Parliament Hill Surgery

113-117 Highgate Road
London
United Kingdom
NW5 1TR

Study participating centre

Caversham Group Practice

4 Peckwater Street
Kentish Town
London
United Kingdom
NW5 2UP

Study participating centre

Prince of Wales Group Surgery

52 Prince of Wales Road
London
United Kingdom
NW5 3LN

Study participating centre

Litchdon Medical Centre

Landkey Road
Barnstaple
United Kingdom
EX32 9LL

Study participating centre
Caen Medical Centre Site
Caen Medical Centre
Braunton
United Kingdom
EX33 1LR

Sponsor information

Organisation

Sussex Partnership NHS Foundation Trust

Sponsor details

Mill View Hospital
Neville Avenue
Hove
England
United Kingdom
BN3 7HZ
+44 (0)1273 621984
ResearchGovernance@sussexpartnership.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<https://www.nhs.uk/Services/hospitals/Overview/DefaultView.aspx?id=2437>

ROR

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

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

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

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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
3. A paper reporting findings from the qualitative data on barriers and facilitators to engagement in outdoor swimming

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.

Patient and Public Involvement (PPI)

The researchers have had three PPI meetings to help us plan this study. They have included people with depression, from diverse backgrounds and people who have found swimming helpful. Two members of our research team are PPI co-applicants and there are three PPI members on an independent panel that helps oversee the study. During the study the researchers will also meet six times with a PPI group who will help with planning how to advertise the study, remove barriers to participation and communicate the findings to the public.

Dissemination

The results will be shared with participants and published in a science journal. A short film and podcast will also be made to spark interest in the larger trial.

Intention to publish date

31/01/2025

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		13/07/2023	17/07/2023	Yes	No