

Health benefits of outdoor physical activity

Submission date 24/05/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/05/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The benefits of regular physical activity for mental and physical health are well known. However, a large proportion of the adult population does not reach the recommended guidelines. Given that, different global and local strategies have been suggested to increase physical activity levels among the population, and the use of outdoor spaces has been largely recommended. Interventions are being developed to improve public health by improving physical activity levels. This study aims to (1) propose an intervention to increase physical activity, through the use of outdoor spaces among inactive adults; (2) monitor mobility patterns and usage of urban spaces; (3) estimate changes in time spent in different intensities of physical activity and sedentary behaviour; (4) determine the perceived and actual benefits of environmental quality on outdoor exercise; (5) estimate the role of environmental quality on the relationship between physical activity and health.

Who can participate?

Physical inactive adults aged between 30-65 years

What does the study involve?

Participants will be required to take part in an 8-week intervention program, and they will be asked to:

1. Wear a small device (9 g) that will be stuck onto their right thigh for 9 consecutive days for 24 hours a day. The device will provide information regarding the participant's physical activity, sedentary behaviour, and standing position
2. Answer online questionnaires regarding physical activity, health status, well-being, sleep quality, and beliefs about green exercise
3. Undergo anthropometric (height, weight, hip and waist circumference), body composition, and blood pressure measurements
4. Undergo fitness and strength tests

All measurements/procedures will be performed two times during the study, namely before the intervention starts and at week 8.

What are the possible benefits and risks of participating?

The findings of the study might be used for the design and implementation of physical activity intervention programmes at a population level, as it is expected that participants involved in the study will improve their fitness and health.

Risks to participants will be minimal, and procedures to minimize them will be adopted. During the anthropometric and body composition measurements, participants can feel some discomfort. To reduce it, measures will be taken in a private room, and each participant will be evaluated by a researcher of the same sex. Participants may feel uncomfortable with some questions from the questionnaires. Participants will be instructed they can skip these questions. During the 6-min walking test, there is a risk of injuries and an injury response protocol will be provided by instructors. During training sessions, participants can feel some discomfort related to the intensity of the physical activity. To avoid this, the programme will be developed so that the participants can manage the training intensity, and instructions will be provided during the exercise.

Where is the study run from?

1. University of Limerick (Ireland)
2. LAB University of Applied Sciences (Finland)
3. Tallinna University (Estonia)

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

June 2022 to January 2024

Who is funding the study?

European Union Horizon 2020

Who is the main contact?

Prof. Alan Donnelly, alan.donnelly@ul.ie

Contact information

Type(s)

Scientific

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information**Scientific Title**

The effects of environmental quality on physical activity participation and health

Acronym

GoGreeRoutes project

Study objectives

Ho: Environmental Quality will not influence the amount of daily moderate-to-vigorous physical activity nor health outcomes.

Hi: Environmental Quality will influence the amount of daily moderate-to-vigorous physical activity and health outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 21/04/2023, Education and Health Science Research Ethics Committee, University of Limerick (Faculty Office, Faculty of Education and Health Sciences, University of Limerick, Limerick, Ireland; +353 (0)61 213081 or 234392; ehs@staffmail.ul.ie), ref: 2023_03_11 EHS

Study design

Interventional multicentre 8-week parallel-group randomized control trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Increasing physical activity in physically inactive adults

Interventions

This is a parallel-group randomized control trial (RCT), where individuals will be the units of analysis. The study will follow the CONSORT guidelines for RCT, and the intervention will take 8 weeks.

Physically inactive adults of all genders, aged between 30-65 years, will be recruited from local city citizens and randomly allocated into two groups (control and intervention, in a 1:1 ratio). The parallel-group randomisation process will be used. Participants will be split into groups, taking into account their sex and age group (30-39 years; 40-49 years; 50-59 years; ≥ 60 years), and then will be randomly allocated into intervention or control groups using the Random Allocation Software.

All participants from both groups (intervention and control) will be measured at two different moments: baseline and at week 8. Measured variables include: a) physical activity, sedentary behaviour, and standing position; b) sleep quality; c) well-being; d) beliefs about green exercise; e) health status; f) anthropometric measurements (waist and hip circumferences, body height and weight) and body composition); f) cardiopulmonary fitness; g) maximum isometric strength; h) blood pressure.

For the intervention, participants will be asked, at the beginning of the study, to choose a route according to their convenience, which they will use to perform the activities suggested in the intervention program. The program consists of participants, using the chosen route, being active (walking or running), following the suggestions made by researchers, and increasing their physical activity levels. They will be requested to get engaged in physical activity at least three times a week for 8 weeks. During this period, the time and intensity of the activity proposed will

gradually increase. A mobile phone app will be used by participants to map the routes they complete in each session of the intervention programme. In addition, participants allocated to the intervention group will be advised to avoid the use of "grey/road routes" during their training sessions and select a green route to perform their training. Moreover, educational information about the benefits of nature-based activities for health will be sent to them. On the other hand, participants allocated to the control group will be advised to avoid the use of "green routes" during their training sessions and select a "grey/road route" to perform their training. Moreover, information about the benefits of physical activity for health will be sent to them.

Intervention Type

Behavioural

Primary outcome(s)

Daily time spent in moderate-to-vigorous physical activity, measured with an accelerometer worn by the participants for 9 consecutive days at baseline and week 8

Key secondary outcome(s)

Measured at baseline and week 8:

1. Daily time spent in light physical activity and sedentary behaviour, measured using an accelerometer
2. Health status, measured using SF-36 questionnaire
3. Sleep quality, measured using Pittsburgh Sleep Quality Index
3. Well-being, measured using WHO well-being questionnaire
4. Beliefs about green exercise, measured using BAGE and BAGE-ID questionnaires
5. Physical health assessments (Body Mass Index (from height and weight), waist and hip circumferences)
6. Body composition, using Bioelectrical Impedance Analysis scale
7. Cardiopulmonary fitness, using 6-min walking test
8. Maximum isometric strength, using handgrip strength test
9. Blood pressure, using sphygmomanometer

Completion date

25/01/2024

Eligibility

Key inclusion criteria

1. Aged between 30-65 years
2. Classified as physically inactive according to WHO guidelines
3. Report no health problems that could impair their involvement in regular physical activities

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

30 years

Upper age limit

65 years

Sex

All

Total final enrolment

155

Key exclusion criteria

Non-residents in the cities where the study will be carried out

Date of first enrolment

08/05/2023

Date of final enrolment

16/10/2023

Locations**Countries of recruitment**

Estonia

Finland

Ireland

Study participating centre**University of Limerick**

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Study participating centre**LAB University of Applied Sciences**

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Sponsor information

Organisation
University of Limerick

ROR
<https://ror.org/00a0n9e72>

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the 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