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Feasibility of an aquatic exercise therapy intervention for falls prevention in older adults

Submission date
04/06/2025

Recruitment status
No longer recruiting

Registration date
04/06/2025

Overall study status
Completed

Last Edited
06/06/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
One-third of people aged 65 years or over fall every year. Falls reduce quality of life, lead to nursing home admissions, cause about 90% of hip fractures and half of deaths due to injury. Several factors that increase fall risk can be improved, such as balance, muscle weakness, mobility and physical function. Exercise on land has a positive effect on these factors, can reduce falls by up to a third. Aquatic exercise has some advantages compared to exercise on land. For example, buoyancy reduces spine and joint loads, and the pressure of the water on the body assists with balance and mobility. The aim of this study was to design and deliver an aquatic exercise intervention for people at high risk of falls. We assess whether people are willing/able to participate and complete the intervention, have a preliminary look at the programme's effects on falls risk and compare it with an established land exercise programme for falls prevention.

Who can participate?
People over 50 years old, with a history of falling (or increased risk of falling), poor gait or balance, or feeling unsteady. They must be living independently and be physically able to take part in an exercise class.

What does the study involve?
For the aquatic exercise group, a 16-week programme with two 30-minute supervised sessions in shallow water (waist-to-chest depth) per week, educational advice on falls prevention and optional recommended exercises to do at home. Three testing sessions, at the start, end, and 6 months after the end of the intervention. Optional weekly/monthly diaries on falls, adverse events and home/other exercise. The land exercise group do the same as above, but a single 60-minute exercise session weekly instead of two 30-minute sessions.

What are the possible benefits and risks of participating?
It is possible that the programme will improve balance, strength, mobility and physical function. This may reduce the risk of having a fall, and could have a positive impact on health and quality of life.
During or after exercising, there is a risk that one may feel some muscle discomfort, soreness or stiffness. This is more likely in the first few weeks, especially if one is unused to exercise. We ask

and encourage participants to report this to us, and we provide suitable advice whenever required. For the aquatic sessions, the poolside floors are sometimes slippery and may present a fall hazard, so we are taking a series of measures to minimise any risk

Where is the study run from?
The study is led by researchers at the University of Edinburgh, in collaboration with Glasgow Caledonian University and Edinburgh Leisure (UK)

When is the study starting and how long is it expected to run for?
October 2022 to September 2025

Who is funding the study?
The study is being funded by the Chief Scientist Office, which is one of the Scottish Government's Health Directorates.

Who is the main contact?
Dr Stelios Psycharakis, stelios.psycharakis@ed.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
HIPS/23/04

Study information

Scientific Title
Feasibility of an AQUAtic exerciSe ThEraPy intervention for falls prevention in older adultS at high risk of falls (AQUA STEPS)- exploration of its effects on falls and risk factors for falls, and comparison with an established land exercise falls prevention programme

Acronym
AQUA STEPS

Study objectives
There are two research questions:
1. Do the key aspects of the aquatic intervention delivery justify a full-scale trial? Such aspects include participant uptake and retention, centre recruitment, procedures implementation and adverse events.
2. Do the outcome measures of falls risk show responsiveness to change for the aquatic intervention? If so, is this responsiveness similar for the aquatic and land interventions?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/09/2023, Moray House School of Education and Sport Ethics Sub-Committee, The University of Edinburgh (Old Moray House, Holyrood Road, Edinburgh, EH8 8AQ, United Kingdom; +44 (0)131 651 4846; MHSES-Ethics@ed.ac.uk), ref: SPSY31082023

Study design
Multi-center interventional non-randomized controlled feasibility trial with two arms

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of falls in older adults who have a high risk of falls

Interventions
The study was not randomised. Participants self-referred to the aquatic arm before being checked for eligibility. For the land arm, participants who had been referred by a health professional to the Steady Steps falls programme and had their eligibility confirmed by the Steady Steps team were invited to participate in the land arm of the study.

A 16-week exercise intervention taking place in shallow water in indoor swimming pools. Two 30-min supervised exercise sessions in the pool per week, plus education on falls prevention, and optional recommended home exercises. Testing at baseline, end of intervention, and after a six-month follow-up period. People self-refer to this intervention arm, are assessed for eligibility and, if confirmed, are allocated to the aquatic group (i.e., not randomised). The comparator is an established land exercise programme ('Steady Steps') that has been running independently for

12 years and service evaluations have indicated positive outcomes. People are referred to this programme by a health professional and eligibility is double-checked and confirmed by the programme team. During the recruitment period, people who are referred to the programme are also invited to join the study by being part of the land exercise group.

The land exercise group do the same as above, but a single 60-min exercise session weekly instead of two 30-min sessions. There is a comprehensive set of assessments at the three timepoints.

Intervention Type
Other

Primary outcome(s)
Feasibility of Aqua Steps, including:
1. Recruitment: ≥70% of participants for the Aqua Steps group recruited within 6 months (measured as people recruited expressed as a percentage of the target of 50)
2. Retention: ≥50% of participants in the Aqua Steps group to remain on the programme until the end of the intervention (measured as the number of participants in the aquatic arm who complete the intervention, expressed as a percentage of the number of participants who started the intervention)
3. Adverse events: <10% of any severe adverse effects deemed to be due to the aquatic intervention (severe adverse effects tracked through weekly diaries and instructor reporting, recorded on adverse event forms, and categorised as mild, moderate and severe)
4. Some evidence of improvement on key risk factors for falls: Evidence of improvement in some of the tests and questionnaires presented as the secondary outcome measures

Key secondary outcome(s))
1. Falls and fallers assessed using questionnaire (number of falls, number of fallers/non-fallers /frequent fallers, and fall rate per person year) at baseline and 6-month follow-up

Measured at baseline, end of intervention and 6-month follow-up:
2. 3 m Timed up and go (functional test, time in seconds)
3. Chair rises in 30 seconds (functional test, number of rises)
4. Functional reach (functional test, distance in cm)
5. Peak isometric knee extension force (strength test, N/kg)
6. Peak isometric knee flexion force (strength test, N/kg)
7. Peak isometric grip force (strength test, N/kg)
8. Postural stability with double and single leg stance (balance test, distance and speed of centre of pressure, in cm and cm/s)
9. Falls efficacy/fear of falling questionnaire (FES-I, range is 16-64 points, greater score = more concerned)
10. Balance confidence questionnaire (Confbal, range is 10-30 points, greater score = lower confidence)
11. Quality of life questionnaire (OPQOL-13, general question: 1-5 points, total score: 13-65 points; greater score = better quality of life)
12. Health status questionnaire (EQ-5D-5L, 0-100 points for visual analogue scale (VAS, greater score = better health), -0.594 to 1.000 for index value (applicable to UK population, greater score =better health)
13. Acceptability questionnaire (adapted version of the theory-driven generic questionnaire of acceptability of healthcare interventions from the participants' perspective; range is 1-5 points, greater score = greater acceptability)

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. People ≥50 years
2. Living independently (e.g. not in care homes)
3. Physically able to take part in an exercise class
4. Being able to self-monitor and regulate the intensity of exercise
5. Having an increased risk of falling or a history of falling, poor gait/balance or feeling unsteady

Participant type(s)
Population, Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 years

Sex
All

Total final enrolment
101

Key exclusion criteria
1. Recent injurious fall without a medical examination
2. Significant cognitive impairment
3. Already participating in an individually prescribed exercise programme
4. Having contra-indications for exercise on land or in the water (e.g. respiratory conditions requiring O2 or compromised lung volumes; skin infections; allergy to chlorine; fear of water; incontinence; severe visual or vestibular disturbances; dementia; vascular conditions affecting sensation; any of the following if uncontrolled: heart disease, blood pressure, hypertension, pain, tachycardia, other uncontrolled mental health conditions)

Date of first enrolment
31/01/2024

Date of final enrolment
17/07/2024

Locations

Countries of recruitment

United Kingdom

Scotland

Study participating centre
Dalry Swim Centre
25-29 Caledonian Crescent
EDINBURGH
United Kingdom
EH11 2AL

Study participating centre
Warrender Swim Centre
55 Thirlestane Road
Edinburgh
United Kingdom
EH9 1AP

Study participating centre
Ainslie Park Leisure Centre
92 Pilton Drive
Edinburgh
United Kingdom
EH5 2HF

Study participating centre
Glenogle Swim Centre
Glenogle Road
Edinburgh
United Kingdom
EH3 5JB

Study participating centre
Penicuik Leisure Centre
9A Carlops Road
Penicuik
United Kingdom
EH26 9EP

Study participating centre
Steady Steps sessions at Christ Church Morningside
6a Morningside Road
EDINBURGH
United Kingdom
EH10 4DD

Study participating centre
Royal Commonwealth Pool
21 Dalkeith Road
EDINBURGH
United Kingdom
EH16 5BB

Study participating centre
Steady Steps sessions at Meggetland Sport complex
4 Meggetland Wynd
EDINBURGH
United Kingdom
EH14 1XN

Study participating centre
Steady Steps sessions at Cramond Kirk Hall
6 Cramond Glebe Road
United Kingdom
EH4 6NS

Study participating centre
Drumbrae Leisure Centre
30 Drum Brae Terrace
Edinburgh
United Kingdom
EH4 7SF

Study participating centre
Gracemount Leisure Centre
22 Gracemount Drive
Edinburgh
United Kingdom
EH16 6RN

Study participating centre
Leith Victoria Leisure Centre
Junction Place
Edinburgh
United Kingdom
EH6 5JA

Study participating centre
Portobello Leisure Centre
57 The Promenade
Edinburgh
United Kingdom
EH15 2BS

Study participating centre
Meadowbank Sports Centre
London Road
Edinburgh
United Kingdom
EH7 6AE

Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)

Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes