

Aquatic thermal therapy for enhancing musculoskeletal strength in older adults with age-related progressive loss of muscle mass and strength

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| Submission date 03/03/2026 | Recruitment status Not yet recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 06/03/2026 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 06/03/2026 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

Italy has a growing older population, with a significant proportion experiencing sedentary lifestyles and reduced physical activity, contributing to sarcopenia, a common geriatric syndrome characterized by a low quantity and quality of muscle mass. Maintaining optimal muscle function and strength is essential for healthy aging, as it correlates with longevity, independence, and reduced risk of falls and chronic diseases such as cardiovascular conditions. Sarcopenia, characterized by the progressive loss of skeletal muscle mass, strength, and function, presents a significant challenge for the aging population, increasing the risk of frailty, disability, and a diminished quality of life. Traditional interventions focus on nutrition, physical therapy, and lifestyle changes, but emerging evidence suggests that thermal therapy, particularly when associated with aquatic exercises, may offer a complementary approach to mitigating sarcopenia's effects. The proposed study investigates the potential benefits of aquatic thermal therapy combined with structured physical exercise in water in improving musculoskeletal strength and overall physical function in older adults diagnosed with sarcopenia.

This study aims to demonstrate the feasibility of conducting a larger scale study on thermal aquatic therapy for sarcopenia. We expect that participants in the intervention group will show significant improvements in gait speed, muscle strength, and overall functional capacity compared to the control group.

In conclusion, this feasibility study seeks to establish whether aquatic thermal therapy is an effective intervention for improving musculoskeletal function in older adults with sarcopenia. If successful, the findings will pave the way for larger clinical trials and the integration of thermal therapy as a standard rehabilitative approach for sarcopenia.

Who can participate?

Older adults aged 65 years and older with sarcopenia will be recruited from the Monticelli Terme rehabilitation centre in Italy, a setting that provides access to inhalation therapies and rehabilitation services.

What does the study involve?

This study will be a randomly allocated and controlled feasibility trial with physical performance, muscle strength, body composition, and quality of life as outcomes. The primary objective of this study is to determine whether thermal therapy combined with aquatic exercises can enhance gait speed (GS) and improve the Short Physical Performance Battery (SPPB) scores in older adults with sarcopenia. Secondary objectives include evaluating the effects on handgrip strength, fat-free mass, and overall quality of life, assessed through validated tools such as the SarQoL questionnaire.

Participants will be allocated into two groups:

- Intervention Group (A): Engaging in a structured thermal aquatic exercise program over nine months, supplemented with general recommendations for a healthy diet (Mediterranean diet).
- Control Group (B): Receiving standard care with lifestyle guidance but without structured aquatic therapy.

The intervention will consist of two weekly sessions of supervised aquatic exercises focusing on warm-up, strength training, and cooldown phases. The progressive resistance training will be adapted to participants' capacities, and perceived exertion will be monitored using the Borg Scale. A six-month follow-up assessment will be conducted to evaluate changes in the primary and secondary outcomes.

What are the possible benefits and risks of participating?

Benefits and risks not provided at time of registration

Where is the study run from?

FoRST - Foundation for Thermal Scientific Research, Italy.

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

September 2026 to March 2028.

Who is funding the study?

FoRST - Foundation for Thermal Scientific Research, Italy.

Who is the main contact?

Prof Nicola Veronese, nicola.veronese@unicamillus.org

Contact information

Type(s)

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Study information

Scientific Title

Aquatic thermal therapy for enhancing musculoskeletal strength in older adults with sarcopenia: a randomized, controlled, feasibility trial

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 27/02/2026, Saint Camillus University Ethics Committee (via Sant'Alessandro 1, Rome, 00161, Italy; +39 06 40 06 40; comitato.etico@pec.it), ref: U00725-2026

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Sarcopenia

Interventions

Engaging in a structured thermal aquatic exercise program over nine months, supplemented with general recommendations for a healthy diet (Mediterranean diet).

After signing the informed consent, the patients will be randomized to two groups, i.e., intervention with thermal therapy or controls. To both groups, general indications to follow a healthy diet, such as the Mediterranean diet, will be given. Patients assigned to the active intervention will follow the intervention proposed for nine months (group A); those randomized to the control group (B) will follow the standard care. About the intervention proposed, physical

activity in water is particularly recommended in older subjects affected by sarcopenia and other musculoskeletal conditions, because of the lower joint stress to which the body is subjected during this type of activity and also, using thermal water is associated with the advantages related to the anti-inflammatory and anti-oedema effect due to the properties of water. Functional assessment will be performed before and after the exercise protocol. Each of the training sessions included in the protocol will consist of three phases. The first part will be dedicated to warm-up, during which mobilization exercises of the main joints and muscle groups will be provided. The middle phase of each unit will involve the performance of strength development exercises involving all major muscle groups. Once the central phase is over, in the last phase of each lesson, defatigue exercises will be performed, with the aim of facilitating and accelerating the disposal phase in order to bring the body back close to basal values and thus promote a more effective and rapid recovery. After the first few weeks of training, it will be possible to gradually increase the work intensity. Keeping the duration of each exercise unchanged, the increase in workload will be achieved by increasing the speed of execution. Patients will be able to describe the subjective perception of exertion through the Borg scale, which involves dividing into a scale of 6 to 20 according to work intensity (where 6 corresponds to no exertion and 20 to maximum exertion): should an individual experience exertion above the value of 16, he or she will be able to slow down and continue the exercise at his or her own pace or possibly stop. We plan an intermediate follow-up visit after six months to check the outcomes of interest. The intervention group will be divided into three groups of 15 people each, in order to maximize the compliance with the therapy.

Intervention Type

Behavioural

Primary outcome(s)

1. Screen for sarcopenia, frailty, and functional decline in older adults measured using the Short Physical Performance Battery (SPPB) at baseline, 3, 6, and 9 months

Key secondary outcome(s)

Completion date

01/03/2028

Eligibility

Key inclusion criteria

Older people (≥ 60 years) affected by sarcopenia

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 years

Upper age limit

150 years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Type 1 and type 2 diabetes mellitus
2. Active cancer
3. Treated with cortisone (as prednisone more than 5 mg/day or equivalent or more)
4. People unable to understand and sign the informed consent
5. Having medical conditions associated with a poor prognosis, i.e., life expectancy less than one year

Date of first enrolment

01/09/2026

Date of final enrolment

01/09/2027

Locations**Countries of recruitment**

Italy

Sponsor information**Organisation**

Fondazione Forst

Funder(s)**Funder type****Funder Name**

Fondazione Forst

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available