

# Exploring the effects of different types of therapeutic exercises in older people with sarcopenia (loss of muscle mass and strength)

<b>Submission date</b> 07/05/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/05/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/07/2020	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Sarcopenia is the age-related loss of skeletal muscle mass, strength and function. This can lead to problems with walking and balance, increased risk of falling, loss of independence, decreased quality of life and disability. The main treatments are medicines, a nutritional approach and physical activity/exercise. Despite this knowledge, there are no guidelines as to what type of therapeutic exercise is the best. Given the above, the aim of this study is to investigate the effects of two different exercise programs; a group-based exercise programme and a home-based exercise programme, both targeted to improve various parameters of quality of life.

### Who can participate?

Adults aged 60 and above who have sarcopenia (pre-sarcopenia, sarcopenia, severe sarcopenia)

### What does the study involve?

The sarcopenic participants are randomly allocated to one of three groups; group-based exercise, individual home based exercise and control group. Those in the first group undergo a supervised group exercise programme. These participants will also walk for at least 100 minutes per week for 12 weeks. Those in the second group undergo a home-based exercise programme. These participants will also walk for at least 100 minutes per week for 12 weeks. Those in the third group receive a leaflet with educational advice about sarcopenia. The same number of exercises are performed by both groups. Participants are assessed before the exercise programme, immediately after (at 12 weeks) and at 12 weeks after the exercise programme has finished (24 weeks). They will also complete questionnaires at 1 year.

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

Participants may benefit from improvements in their symptoms. There are no notable risks of participating. Participation in the study is voluntary. Participants can refuse to participate or stop participating at any time. All information obtained for this study is used for research purposes only and will be kept strictly confidential.

Where is the study run from?

This study is run in 3 different sites in the small county of Achaia in mainland Greece.

1. University Hospital of Patras
2. Technological Educational Institute (TEI) of Western Greece
3. 2nd Open Care Centre of Patras

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

February 2017 to February 2018

Who is the main contact?

1. Mrs Maria Tsekoura (Scientific)
2. Professor John Gliatis (Scientific)

## Contact information

### Type(s)

Public

### Contact name

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### Type(s)

Public

### Contact name

Prof John Gliatis

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## Additional identifiers

Protocol serial number

2011

## Study information

**Scientific Title**

The relationship between therapeutic exercise and parameters of quality of life in patients with sarcopenia

**Acronym**

ESARQOL

**Study objectives**

Patients with sarcopenia could benefit from a group-based and a home-based exercise programme

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Technological Educational Institute of Western Greece ethics committee, 13/03/2017, 4052/13-03-2017

**Study design**

Single-blind randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Not Specified

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

Sarcopenia

**Interventions**

Participants are randomized into three groups – Group A, Group B and Group C

Group A: Participants receive supervised group therapeutic exercises two times per week for 12 weeks. Furthermore they walk for 100 min per week (minimum).

Group B: Participants receive home therapeutic exercises for 12 weeks. Furthermore they walk for 100 min per week (minimum).

Group C: Participant receive a leaflet with educational advice on diet, lifestyle and activity.

**Intervention Type**

Behavioural

**Primary outcome(s)**

1. Quality of life is assessed using the Sarcopenia Quality of Life (SarQol) questionnaire at baseline, 12 weeks, 24 weeks and 12 months
2. Muscle strength is assessed with Biodex isokinetic dynamometer for knee flexors and extensors at baseline, 12 weeks and 24 weeks
3. Gait speed is assessed using the 4-m test at baseline, 12 weeks and 24 weeks

**Key secondary outcome(s)**

1. Function is assessed using the Timed Up and Go Test and sit to stand test (5 repetitions) at baseline, 12 weeks and 24 weeks
2. Fatigue is assessed using the FSS questionnaire at baseline, 12 weeks, 24 weeks and 12 months
3. Fear of falling is assessed using the FES questionnaire at baseline, 12 weeks, 24 weeks and 12 months
4. Body composition and Muscle mass is assessed using Bioelectrical impedance analysis (Tanita BC 601) at baseline, 12 weeks and 24 weeks
5. Calf measurement is assessed in cm at baseline, 12 weeks and 24 weeks
6. Depression and anxiety is assessed using the HADS questionnaire at baseline, 12 weeks and 24 weeks
7. Hand grip muscle strength is assessed with handheld grip dynamometer (SAEHAN) at baseline, 12 weeks and 24 weeks
8. Balance is assessed with the Berg Balance Scale at baseline, 12 weeks and 24 weeks
9. Nutrition is assessed with the SNAG questionnaire at baseline, 12 weeks, 24 weeks and 12 months post exercise
10. Physical activity is assessed with PASE questionnaire at baseline
11. Mental state is assessed with the Mini Mental Scale at baseline

**Completion date**

20/03/2018

## Eligibility

**Key inclusion criteria**

1. Sarcopenic patients according the European Working Group on Sarcopenia in Older People criteria (EWGSOP)
2. Aged 60 years and older
3. Not currently engaged in exercise training (within last 3 months)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Total final enrolment**

54

**Key exclusion criteria**

1. Cognitive impairments
2. Neurological disorders
3. Pacemaker fitted
4. Cardiovascular diseases or high blood pressure not controlled with medication

5. Surgery on lower limbs affecting gait
6. Medical or other musculoskeletal problems that could affect ability to complete objective assessments, or exercise with safety
7. Currently engaged in exercise training (within last 3 months)

**Date of first enrolment**

14/03/2017

**Date of final enrolment**

20/02/2018

## **Locations**

**Countries of recruitment**

Greece

**Study participating centre**

**University Hospital of Patras**

Rio

Patra

Greece

26500

**Study participating centre**

**Technological Educational Institute (TEI) of Western Greece, Physiotherapy department**

Psaron 6

Aigio

Greece

25100

**Study participating centre**

**2nd Open Care Center for the elderly**

Kazantzaki Nikou 21

Patra

Greece

26442

## **Sponsor information**

**Organisation**

Technological Educational Institute (TEI) of Western Greece

ROR

<https://ror.org/01mymm084>

## Funder(s)

### Funder type

Not defined

### Funder Name

investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (Laboratory of Human Assessment and Rehabilitation repository) accessible by study contact Maria Tsekoura and her supervisor, Professor John Gliatis. Data will be available from Maria Tsekoura on reasonable request. All participants agreed to participate and signed an informed consent form. Names of participants on the datasets are with codes, ensuring anonymisation. Statistical Analyses described are performed using IMB SPSS Statistics 20.0.

### IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	26/11/2018	27/07/2020	Yes	No