

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

Submission date 07/05/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/05/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/07/2020	Condition category 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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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?
Results article	results	26/11/2018	27/07/2020	Yes	No