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

| Submission date   | Recruitment status  No longer recruiting | <ul><li>Prospectively registered</li></ul> |  |  |
|-------------------|--|--|--|--|
| 07/05/2018        |  | ☐ Protocol                                 |  |  |
| Registration date | Overall study status                     | Statistical analysis plan                  |  |  |
| 16/05/2018        | Completed                                | [X] Results                                |  |  |
| Last Edited       | Condition category                       | Individual participant data                |  |  |
| 27/07/2020        | Musculoskeletal Diseases                 |  |  |  |

#### 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

Mrs Maria Tsekoura

#### Contact details

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#### Type(s)

Public

#### Contact name

**Prof John Gliatis** 

#### Contact details

University Hospital of Patra PATRA Greece 26504 2613603000 gliatis@hotmail.com

# Additional identifiers

EudraCT/CTIS number

**IRAS** number

ClinicalTrials.gov number

#### Secondary identifying numbers

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

### Secondary study design

Randomised controlled trial

#### Study setting(s)

Community

#### Study type(s)

**Not Specified** 

#### Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

#### 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 measure

- 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

#### Secondary outcome measures

- 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

#### Overall study start date

17/02/2016

#### 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** 

#### Age group

#### Senior

#### Sex

Both

#### Target number of participants

60

#### 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

#### Sponsor details

Psaron 6 Aigio Greece 25100 0030 26910 61150 ftherapia@teiwest.gr

#### Sponsor type

University/education

#### **ROR**

https://ror.org/01mymm084

# Funder(s)

# Funder type

Not defined

#### **Funder Name**

investigator initiated and funded

# **Results and Publications**

#### Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

# Intention to publish date

20/09/2018

#### 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 SPPS 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              |