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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

Registration date
16/05/2018

Overall study status
Completed

Last Edited
27/07/2020

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Mrs Maria Tsekoura

Contact details
Psaron 6
Aigio
Greece
25100
+302691061150
mariatsekoura@hotmail.com

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