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Sarcopenia and exercise in seniors

Submission date
18/05/2017

Recruitment status
No longer recruiting

Registration date
01/06/2017

Overall study status
Completed

Last Edited
01/07/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Sarcopenia is the loss of skeletal muscle mass and strength as a result of ageing. It is linked with an increased risk of disability, falls and numerous other adverse health outcomes, including death. Effective interventions are needed to improve physical functioning and sarcopenia among older people. Among preventive interventions, exercise has been particularly studied, but studies focusing on sarcopenic elders specifically are scarce. A previous study tested a new promising way to improve gait (manner of walking), muscle strength, balance, and prevent falls in older people using a music-based multitask training intervention called Jaques-Dalcroze Eurhythmics. It is not known whether this exercise intervention is effective for sarcopenic older adults. Also, it is unclear whether this particular type of exercise improves cognitive (mental) function. The aim of this study is to assess the effectiveness of Jaques-Dalcroze Eurhythmics exercise training in older adults with sarcopenia.

Who can participate?
Adults aged 65 and over with sarcopenia

What does the study involve?
Participants are randomly allocated to an intervention group or a control group. Participants in the intervention group attend supervised, structured, progressive, 60-min sessions of music-based exercise training two times per week for 12 months. The control group do not receive the exercise training during the study period. All participants are followed-up for 12 months and are asked to attend three clinical visits at the start of the study, and after 6 and 12 months. Clinical visits include assessment of physical performance, skeletal muscle health, sarcopenia status, cognitive performance, incidence of falls and injuries, mobility disability, and quality of life. In addition, some of the participants undergo MRI scans to assess brain, nervous system and muscle function at the start of the study and after 12 months.

What are the possible benefits and risks of participating?
Participants may benefit from the Jaques-Dalcroze Eurhythmics exercise program and receiving information on different topics of relevance to older adults. Furthermore, the results of this study might reveal important information for future sarcopenic older adults. There are no notable risks involved with taking part other than the general risks associated with exercising (e. g., minor discomfort such as temporary muscle soreness). Jaques-Dalcroze exercise training has been proved to be feasible and well tolerated even among frail seniors in previous studies.

Where is the study run from?
Geneva University Hospitals (Switzerland)

When is study starting and how long is it expected to run for?
March 2017 to December 2019

Who is funding the study?
Swiss National Science Foundation (Switzerland)

Who is the main contact?
Dr Andrea Trombetti
Andrea.trombetti@hcuge.ch

Contact information

Type(s)
Scientific

Contact name
Dr Andrea Trombetti

Contact details
Division of Bone Diseases
Department of Internal Medicine Specialties
Geneva University Hospitals
Rue Gabrielle-Perret-Gentil 4
Geneva
Switzerland
1211
+41 (0)795 538 376
andrea.trombetti@hcuge.ch

Additional identifiers

Protocol serial number
CCER2017-00437

Study information

Scientific Title
SARCopeniA and exeRcisE in older adults: a randomized controlled trial

Acronym
SARCARE

Study objectives

The purpose of this study is to evaluate the efficacy and the possible mechanisms underlying the efficacy of Jaques-Dalcroze Eurhythmics exercise training in older adults with sarcopenia. The main aim is to test whether Jaques-Dalcroze exercise training is able to counteract physical limitations in older adults with sarcopenia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Ethics Committee Geneva (Commission cantonale d'Ethique de la Recherche du Canton de Genève), 21/03/2017, ref: 2017-00437

Study design
Prospective single-centre single-blind two-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Participants will be randomized according to a computer-generated randomization sequence in a 1:1 ratio to either:
1. The music-based multitask exercise intervention (i.e., Jaques-Dalcroze Eurhythmics), which will consist of supervised, structured, progressive, twice-weekly, 60-min sessions for 12 months
2. The control group, who will not receive the music-based multitask exercise intervention during the study period
Participants from both study groups will also attend quarterly workshops regarding health-related issues (i.e., 4 workshops over 12 months; 60-min duration).

All subjects are followed-up for 12 months from randomization and asked to attend three clinical visits in addition to the screening visit (i.e., at baseline, 6 months and 12 months). Clinical visits include assessment of physical performance, skeletal muscle health, sarcopenia status, cognitive performances, incidence of falls and injurious falls, mobility disability, and quality of life. In addition, brain and neuromuscular function are specifically addressed among a subgroup of trial participants (i.e., exploratory sub-study), which, in particular, involves functional magnetic resonance imaging (fMRI) at baseline and 12 months.

Intervention Type
Other

Primary outcome(s)
Physical performance, measured with the Short Physical Performance Battery (SPPB) score at baseline, 6 and 12 months

Key secondary outcome(s))

1. Skeletal muscle health (including muscle strength and muscle mass, assessed by dynamometry and dual-energy X-ray absorptiometry, respectively) at baseline, 6 and 12 months
2. Sarcopenia status according to cut-off points for sarcopenia at baseline, 6 and 12 months
3. Other physical performances (including gait speed, five times sit-to-stand test time and Timed Up & Go tests) at baseline, 6 and 12 months
4. Balance (including simplified Tinetti test) measured at baseline, 6 and 12 months
5. Cognitive performance, measured with a comprehensive neuropsychological battery assessing different aspects of executive functioning at baseline, 6 and 12 months
6. Incidence of falls and injurious falls, measured with prospective daily recording using calendars at baseline, 6 and 12 months
7. Mobility disability (including 400m walk test) at baseline, 6 and 12 months
8. Quality of life (including SF-36, SarQol) at baseline, 6 and 12 months

Completion date
31/03/2020

Eligibility

Key inclusion criteria
1. Age ≥65 years (no upper age limit)
2. Short Physical Performance Battery (SPPB) score between 3 and 9, inclusive
3. Presence of low muscle mass according to the Baumgartner definition
4. Able to complete the 400 m walk test within 15 minutes without sitting or the help of another person, or the use of a walker
5. Willingness to give informed consent, to be randomized to one of the two study groups, and comply with all study requirements

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
196

Key exclusion criteria
People are excluded from participation in the study for any condition likely to affect the safety of the intervention and/or limit lifespan, or factors that may limit adherence to intervention or affect conduct of the trial (e.g., physical limitations should not be clearly attributable to the direct effect of a specific disease). In particular, exclusion criteria applied are:
1. Resides in a nursing home or is hospitalized
2. Diagnosis of dementia or score <21 on the MMSE
3. Serious neurological, neuromuscular or orthopaedic condition (e.g.,Parkinson's disease)

4. Serious cardiovascular or pulmonary condition (including myocardial infarction in previous 6 months) or development of chest pain or severe shortness of breath on the 400 m walk test
5. Participation in a supervised music-based multitask exercise program in the past 12 months

Date of first enrolment
01/06/2017

Date of final enrolment
10/02/2019

Locations

Countries of recruitment
Switzerland

Study participating centre
Geneva University Hospitals
Division of Bone Diseases
Department of Internal Medicine Specialties
Geneva
Switzerland
1211

Sponsor information

Organisation
Geneva University Hospitals

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Government

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung (Ref: 32003B_166690)

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date