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Effects of exercise and coenzyme Q10 supplementation on muscular functionality in elderly

Submission date
25/08/2017

Recruitment status
No longer recruiting

Registration date
20/10/2017

Overall study status
Completed

Last Edited
26/10/2017

Condition category
Other

[ ] 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 (loss of muscle relative to aging) has been proposed as a geriatric (older people) syndrome characterized by the presence of low muscle mass combined with low muscle function. It is estimated that muscle loss occurs at a rate as fast as 1% per year starting at age 40. This condition is common in elderly, in Mexico the prevalence of sarcopenia is 16.7% to 33.6%. People with sarcopenia have a higher risk of disability, complications of chronic diseases, increased length of stay in hospital and mortality. It is important to promote treatments to improve their strength and functionality. There are no treatment guidelines for sarcopenia but scientific evidence suggests that resistance exercises improve muscle strength and physical performance. On the other hand, the effects of nutritional supplementation are controversial and some metabolic agents have been sugested to prevent or treat sarcopenia. Coenzyme Q10 is an antioxidant and an essential component in the production of ATP that could preserve physical performance and reduce oxidative stress in older people. The aim of this study is evaluate the changes in muscle strength, muscle mass and functionality after and intervention with resistance exercise and coenzyme Q10.

Who can participate?
Adults aged 60-74 years old who have controlled chronic degenerative diseases.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group receive resistance exercises and receive a Q10 supplementation daily in the morning for three months. Those in the second group receive the resistance exercise and take a capsule of placebo (a dummy) medication daily in the morning for three months. Those in the third group receive one capsule of Q10 supplementation daily for three months. Those in the fourth group receive one capsule of a placebo daily in the morning for three months. The resistance exercise included there sessions per week. Participants have their muscle mass and strength measured before and after the programme.

What are the possible benefits and risks of participating?
Participants in the resistance exercise groups may benefit from increasing their muscle strength and functionality. Participants who receive the coenzyme Q10 supplementation can improve their energy and benefit from the antioxidant effect of the coenzyme. Participants also receive recommendations to improve their energy and protein intake. There are no direct risks in the resistance exercise groups due to the supervision of the exercises. Participants in the supplementation groups may experience gastrointestinal symptoms, nausea, diarrhea, loss of appetite, burning and abdominal discomfort.

Where is the study run from?
Gerontology Research Unit, FES Zaragoza (Mexico)

When is the study starting and how long is it expected to run for?
May 2014 to August 2017

Who is funding the study?
National Autonomous University of Mexico (Mexico)

Who is the main contact?
Dr Víctor Manuel Mendoza-Nuñez

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

IN306213

Study information

Scientific Title
Effects of resistance exercise and coenzyme Q10 supplementation on muscle mass, muscle strength and functionality in adult community-dwelling elderly Mexicans

Study objectives
Participants with resistance exercise intervention and supplementation with coenzyme Q10 will lead to a greater improvement of the muscle strength, muscle mass and functionality compared with the group of only exercise intervention, coenzyme Q10 supplementation or placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bioethics and Biosafety Committee of the Research Committee of “Facultad de Estudios Superiores Zaragoza, UNAM”, 12/01/2015, ref: 25/11/SO/3.4.3

Study design
Interventional non randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Dynapenia, presarcopenia, sarcopenia

Interventions
All participants provide written informed consent before inclusion in the study. Participants are randomly allocated to one of four groups:
Group 1: Participants receive resistance exercise and receive the intake of coenzyme Q10 supplementation (one capsule of 200mg) daily in the morning for three months
Group 2: Participants receive resistance exercise and intake one capsule of placebo (200mg) daily in the morning for three months.
Group 3: Participants intake one capsule of conenzyme Q10 supplementation (200mg) daily in

the morning for three months
Group 4: Participants intake one capsule of placebo (200mg) daily in the morning for three months.

Resistance exercise:
Participants who receive the resistance exercise receive the one hour sessions three times per week divided in 4 sections:
1. Warm up and stretching (5 minutes): flexions and streching neck, shoulders, arms, legs and ankles for 10-20 seconds each one with resting intervals of 5 seconds
2. Dancing (10 minutes)
3. Resistance exercises (30-40 minutes): Participants start doing 2-3 sets for each muscle groups: upper limbs, lower limbs, trunk, chest and abdomen. Each set will have 6 repetitions with dead weight and resting 4 seconds between each one. Progression of weight added to the resistance exercise will be made individually. 1) Cool down and stretching (5 minutes): flexions and streching neck, shoulders, arms, legs and ankles for 10-20 seconds each one with resting intervals of 5 seconds. Coenzyme Q10

Participants have their mass and muscular strength measured before and after the intervention.

Intervention Type
Mixed

Primary outcome measure
1. Muscle strength is measured using the HGS using Jamar hand-held dynamometer (Lafayette) Maximum value of three repetitions with the dominant hand was recorded, with 1 minute between measurements to avoid fatigue at baseline and three months
2. Muscle mass is measured by bioelectrical impedance using four-pole mono-frequency equipment (50-kHz, Quantum X, RJL System)at baseline and three months
3. Functionality is evaluated by gait speed (400-m walk test) at baseline and three months

Secondary outcome measures
Phase angle is measured using bioelectrical impedance using four-pole mono-frequency equipment (50-kHz, Quantum X, RJL System) at baseline and three months.

Overall study start date
01/05/2014

Completion date
01/08/2017

Eligibility

Key inclusion criteria
1. Adults between 60-74 years
2. Chronic degenerative diseases controlled
3. Provision of informed consent

Participant type(s)
Healthy volunteer

Age group

Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Participation in any physical training program.
2. Chronic illness which contributed to loss of muscle mass (arthritis, cancer, renal failure, HIV)
3. Cardiac conditions that made patients unable to perform exercise

Date of first enrolment
01/11/2014

Date of final enrolment
30/05/2017

Locations

Countries of recruitment
Mexico

Study participating centre
Gerontology Research Unit, FES Zaragoza (Unidad de Investigación en Gerontología, FES Zaragoza, UNAM)
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Sponsor information

Organisation
National Autonomous University of Mexico

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Sponsor type
University/education

ROR
https://ror.org/01tmp8f25

Funder(s)

Funder type
University/education

Funder Name
National Autonomous University of Mexico

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other