ISRCTN62824599 https://doi.org/10.1186/ISRCTN62824599

Effect of resistance exercise on plasma interleukin 6 (IL-6) and tumour necrosis factor-alpha (TNF-alpha), knee extensor muscle strength and functional capacity in older women

Submission date
27/10/2009

Recruitment status
No longer recruiting

Registration date
08/12/2009

Overall study status
Completed

Last Edited
14/02/2012

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NCT

Study information

Scientific Title
Effect of resistance exercise on plasma interleukin 6 (IL-6) and tumour necrosis factor-alpha (TNF-alpha), knee extensor muscle strength and functional capacity in older women: a single-blind randomised controlled cross-over trial

Study objectives
The overall aim of the present study is to assess the impact of a programme of exercises performed with 75% of 1RM for ten weeks, on the plasma levels of interleukin 6 (IL-6) and tumour necrosis factor-alpha (TNF-alpha), knee extensors muscle strength and functional capacity of community-dwelling older women, particularly in those classified as pre-frail.

The specific research questions are:
1. What are the effects of a programme of ten-weeks of resistance training on muscle strength, IL-6, TNF-alpha and functionality?
2. Is there an association between knee extensor muscle strength and the plasma levels of IL-6 and TNF-alpha in pre-frail older women, evaluated after a ten-week resistance training programme?
3. Variables: Do knee extensor muscle strength and plasma levels of IL-6 and TNF-alpha influence the functional capacity in pre-frail older women evaluated after a ten-week resistance training programme?
4. Is there a change in knee extensor muscle strength, plasma levels of IL-6 and TNF-alpha and functional capacity in pre-frail older women after a ten-week resistance training programme?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Research, Federal University of Minas Gerais (Universidade Federal de Minas Gerais [UFMG]) approved on the 5th December 2007 (ref: ETIC 321/2007)

Study design
Single-blind randomised controlled cross-over trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Quality of life

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

Health condition(s) or problem(s) studied
Knee extensor muscle strength/functional capacity in older women

Interventions
The subjects will participate in a strength training programme three times a week, lasting 60-minute each session, for 10 weeks. Two major muscle groups (knee extensors and flexors) will both be trained in three sets of eight repetitions, at 75% of 1RM. Each participant will be tested at baseline, after the end of the training programme and 10 weeks after programme completion. Every training session starts with ten minutes of warm-up and ends with ten minutes of cool-down. Bi-weekly, the 1RM test is repeated to guarantee the correct percentual, in case of gains. The exercises are done with ankle weights. One group will be evaluated, will receive the intervention and then, after ten weeks, will be evaluated again. Another group will be evaluated, will maintain their regular activities during ten weeks when they will be evaluated again, and then will start the intervention as in the first group (cross-over).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Plasma levels of IL-6 and TNF-alpha measured by enzyme-linked immunosorbent assay.

All primary and secondary outcomes will be assessed at baseline (before intervention), after intervention and 10 weeks post-intervention.

Secondary outcome measures
1. Static and isokinetic muscle strength of the knee extensors and flexors measured electronically by Byodex 3 Pro (Biodex Medical System, USA)
2. Functional capacity, measured by the 10-meter walk test and the Timed Up and Go test (TUG)
3. Clinical outcomes (pain, fatigue and self-perceived health)

All primary and secondary outcomes will be assessed at baseline (before intervention), after intervention and 10 weeks post-intervention.

Overall study start date
01/12/2009

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. Female
2. Community-dwelling
3. Aged equal to or higher than 65 years-old
4. Classified as pre-frail according to the phenotype

Participant type(s)
Patient

Age group
Senior

Sex
Female

Target number of participants
26

Key exclusion criteria
1. Elderly previously submitted to orthopedic surgeries on lower limbs and/or with a history of fracture
2. Those whom were not able to walk without support
3. Carriers of neurological diseases
4. Those whom presented any type of inflammatory disease in an acute stage
5. Neoplasia in activity in the last five years
6. Those whom were using medication that affect largely the immunological system
7. Those whom presented cognitive impairments detectable by the Mini-Mental State Examination (MMSE)

Date of first enrolment
01/12/2009

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
Brazil

Study participating centre
Programa de Pós Graduação em Ciências da Reabilitação
Belo Horizonte - MG
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Sponsor information

Organisation
National Council of Scientific and Technological Development (CNPq) (Brazil)

Sponsor details
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Sponsor type
Government

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ROR
https://ror.org/03swz6y49

Funder(s)

Funder type
Government

Funder Name
National Council of Scientific and Technological Development (Conselho Nacional de Desenvolvimento Cientifico e Tecnológico [CNPq]) (Brazil)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/07/2010		Yes	No
Results article	results	01/11/2010		Yes	No
Results article	results	01/08/2011		Yes	No