

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

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Registration date 08/12/2009	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 14/02/2012	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Female

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

Brazil

31270-901

Sponsor information

Organisation

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

ROR

<https://ror.org/03swz6y49>

Funder(s)

Funder type

Government

Funder Name

Results and Publications

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?
Results article	results	01/11/2010		Yes	No
Results article	results	01/08/2011		Yes	No
Protocol article	protocol	28/07/2010		Yes	No