

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of massed vs. distributed lower body strength training on whole body function in elderly women

Protocol summary

Study aim

To compare the effect of massed vs. distributed lower body strength training on whole body function in elderly women

Design

Clinical trial with a control group, with parallel groups, single-blind, block randomization, on 45 participants.

Settings and conduct

This is a Quasi-experimental study with a per-test-posttest design. Upper and lower body strength tests via digital dynamometer, body composition via Akren BIA101 BIVA, gait performance via optogate device and blood pressure and resting heart rate via digital sphygmomanometer will be measured in the laboratory of Bojnourd University. Several functional tests will be used to determine the function movement performance of the participants. Single-blinding will be achieved in such a way that no information will be provided to the participants on which training group they will be placed in.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having no regular training over the past six months, healthy women 55 years old and / or older; Exclusion criteria: Having joint and physiological problems, having a history of falling.

Intervention groups

45 healthy, but inactive elderly women will be divided into three groups: Distributed training group (15 people) who will train five times a week, massed training group (15 people) who will train three times a week, the training includes a strength training program, and the control group (15 people) who will not do any exercise training.

Main outcome variables

Upper and lower body muscle strength, functional whole body

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201030049193N3**

Registration date: **2021-07-03, 1400/04/12**

Registration timing: **prospective**

Last update: **2021-07-03, 1400/04/12**

Update count: **0**

Registration date

2021-07-03, 1400/04/12

Registrant information

Name

Mahdi Hosseinzadeh

Name of organization / entity

Sport Sciences Research Institute of Iran

Country

Iran (Islamic Republic of)

Phone

+98 21 7714 6478

Email address

metti@ssrc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-11, 1400/04/20

Expected recruitment end date

2021-08-11, 1400/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of massed vs. distributed lower body strength training on whole body function in elderly women

Public title

Effect of massed vs. distributed lower body strength training on whole body function

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

women who are 55 years old and/or older Having no regular training over the past six months

Exclusion criteria:

Having a history of falling Having joint and physiological problems

Age

From **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Three groups of female participants will be randomly recruited to participate in this study. The block randomization method will be used to create a random sequence to assign participants randomly in one of the three groups. In this method, blocks of 6 all possible combinations (8 modes) are created, then these blocks are numbered and randomly selected and placed one after the other, and thus, participants will be assigned into two groups A and B (as intervention), and group C (as control).

Blinding (investigator's opinion)

Single blinded

Blinding description

In order for single blinding, some general information about how to perform the training and testing methods will be given to all the participants. However no information will be provided to the participants on which training group they will be placed in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sport Sciences Research Institute

Street address

No. 3,Fifth, Mir Emad St.,Ostad Motahari St

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2020-04-12, 1399/01/24

Ethics committee reference number

IR.SSRC.REC.1399.014

Health conditions studied

1

Description of health condition studied

Distributed and massed strength training of the lower body, whole body function (lower and upper body)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Lower body strength performance evaluated by hamstring and quadriceps muscles strength.

Timepoint

The outcome measures will be recorded at three time points including a baseline- pretest measurements at the start of the study, a mid test session after eighth weeks of training and finally a post test which will be recorded after finishing the training after the week twelve.

Method of measurement

Digital dynamo-meter device made in Iran, 30 second chair stand test

2

Description

Strength of the upper body limbs, Biceps muscles

Timepoint

The outcome measures will be recorded at three time points including a baseline- pretest measurements at the start of the study, a mid test session after eighth weeks of training and finally a post test which will be recorded after finishing the training after the week twelve.

Method of measurement

Digital dynamo-meter device made in Iran, 30 second arm Curl Test

3

Description

Proprioception of the Knee joint, and elbow joint

Timepoint

The outcome measures will be recorded at three time points including a baseline- pretest measurements at the start of the study, a mid test session after eighth weeks of training and finally a post test which will be recorded after finishing the training after the week twelve.

Method of measurement

Plastic goniometer with accuracy of measuring at least 1 degree

4

Description

Functional Gait Assessment

Timepoint

The outcome measures will be recorded at three time points including a baseline- pretest measurements at the start of the study, a mid test session after eighth weeks of training and finally a post test which will be recorded after finishing the training after the week twelve.

Method of measurement

Optogait recording with a frequency of 1000 Hz and an accuracy of 1 cm Made in Italy, 10 m walking test

5

Description

Pain score

Timepoint

The outcome measures will be recorded at three time points including a baseline- pretest measurements at the start of the study, a mid test session after eighth weeks of training and finally a post test which will be recorded after finishing the training after the week twelve.

Method of measurement

Visual Analogue Scale, Timed 10-stair climbing and descending

6

Description

Blood pressure

Timepoint

The outcome measures will be recorded at three time points including a baseline- pretest measurements at the start of the study, a mid test session after eighth weeks of training and finally a post test which will be recorded after finishing the training after the week twelve.

Method of measurement

Digital Sphygmomanometer

7

Description

Anthropometric indices

Timepoint

The outcome measures will be recorded at three time points including a baseline- pretest measurements at the start of the study, a mid test session after eighth weeks

of training and finally a post test which will be recorded after finishing the training after the week twelve.

Method of measurement

Weight measurement using a digital scale made in China with an accuracy of 100 grams. Measuring the circumference of the arm, forearm, thigh, leg using a tape meter made in Iran with an accuracy of 0.1 cm.

Body composition recorded using the BIA101 BIVA Akren made in Italy

8

Description

Resting heart rate

Timepoint

The outcome measures will be recorded at three time points including a baseline- pretest measurements at the start of the study, a mid test session after eighth weeks of training and finally a post test which will be recorded after finishing the training after the week twelve.

Method of measurement

Digital Sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Consisting of 15 participants who will be training using a distributed strength program, including 5 sessions per week and each session will be 45-60 minutes of training. The principle of overload will be considered for all the 12 weeks of training. This program consists of three parts: warm-up for lower limbs (part I), 10-minute of general stretching movements. Strength training of lower limbs (part II), The program in the first month of training will be based on the individual's weight, the second month with low resistance stretch bands, the third month with medium and high resistance stretch bands. A cool down (part III), consisting of 10 minutes walking, standing and sitting stretching movements will finally be completed.

Category

Rehabilitation

2

Description

Intervention group 2: Consisting of 15 participants will be training in a massed strength training protocol. The protocol includes 3 sessions per week and each session will be 45-60 minutes of training. The principle of overload will be considered for all the 12 weeks of training. This program consists of three parts: warm-up for lower limbs (part I), including 10-minute stretching movements. Strength training of the lower body limbs (part II), The first month training will be implemented based on the individual's weight, the second month with low resistance stretch bands, the third month with

medium and high resistance stretch bands. A cooling down (part III) program, including 10 minutes walking, standing and sitting stretching movements will finally be completed.

Category

Rehabilitation

3**Description**

Control group: Consisting of a group of 15 participants who will continue to their regular daily living but will attend to the three sessions of pre, mid, and post test sessions.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Univcity of Bojnord

Full name of responsible person

Mahta Sardroodian

Street address

4th Km along the Road to Esfarayen, Bojnord, North

City

Bojnord

Province

North Khorasan

Postal code

9453155111

Phone

+98 58 3220 1000

Fax

+98 58 3228 4605

Email

Info@ub.ac.ir

Web page address

https://ub.ac.ir/en/home

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Univcity of Bojnord

Full name of responsible person

Hasan Sajjadi

Street address

4th Km along the Road to Esfarayen, Bojnord, North Khorasan

City

Bojnord

Province

North Khorasan

Postal code

9453155111

Phone

+98 58 3220 1000

Fax

+98 58 3228 4605

Email

Info@ub.ac.ir

Web page address

https://ub.ac.ir/en/home

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Univcity of Bojnord

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Sport Sciences Research Institute of Iran

Full name of responsible person

Mahdi Hosseinzadeh

Position

Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Sport Sciences

Street address

No. 3, 5th Ahhey, Miremad Street, Motahhari Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1587958711

Phone

+98 21 7714 6478

Fax

+98 21 8873 9092

Email

metti@ssrc.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Sport Sciences Research Institute of Iran

Full name of responsible person

Mahdi Hosseinzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

علوم ورزشی

Street address

No. 3, 5th Ahhey, Miremad Street, Motahhari Street,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1587958711

Phone

+98 21 7714 6478

Fax

+98 21 8873 9092

Email

metti@ssrc.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Sport Sciences Research Institute of Iran

Full name of responsible person

Mahdi Hosseinzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Sciences

Street address

No. 3, 5th Ahhey, Miremad Street, Motahhari Street,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1587958711

Phone

+98 21 7714 6478

Fax

+98 21 8873 9092

Email

metti@ssrc.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

We share data files including personal information and data related to pre-test and post-test in a coded and unanimous folder by the person in charge, Dr. Mehdi Hosseinzadeh, on the website of Bojnord University.

When the data will become available and for how long

Start the access period as soon as the results are published

To whom data/document is available

It will be available to all research groups as well as all other people who are interested

Under which criteria data/document could be used

The data can be used for further studies as well as in all research groups, and any kind of research analysis and use is allowed on the data, and under the conditions that the person use it should refer to us (the paper published), this data will be provided to them.

From where data/document is obtainable

Refer to the person responsible for answering Dr. Mehdi Hosseinzadeh: Address: No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran, Iran Sport Science Researcher Institute Postal Code 1587958711 Email: metti@ssrc.ac.ir Phone: 009877146478 : 00988739092

What processes are involved for a request to access data/document

The applicant will send his/her application to the e-mail address of Dr. Mehdi Hosseinzadeh (metti@ssrc.ac.ir) and Dr. Hosseinzadeh will provide the information to his/her after the necessary checks

Comments