Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of long-term effects of active range of motion exercises with and without whole-body vibration on skeletal muscle index and physical performance in elderly population with sarcopenia

Protocol summary

Study aim
To determine the effects of Whole-Body Vibration (WBV) training on sarcopenia in the elderly population

Design
Assessor-blinded Randomized Control Trial of 56 community-dwelling older adults

Settings and conduct
Assessor-blinded Randomized Control Trial of 56 community-dwelling older adults at National Institute of Rehabilitation Science, Islamabad, Pakistan

Participants/Inclusion and exclusion criteria
Individuals with age 60 and above, meeting sarcopenia diagnostic criteria based on the European Working Group on Sarcopenia in Older Population (EWGSOP2) algorithm for case-finding and diagnosis with a negative Romberg's sign. Anyone meeting “severe” sarcopenia diagnostic criteria, having uncontrolled medical conditions, lower limb implants or taking drugs that affect neuromuscular system, won't be included.

Intervention groups
Intervention group will receive 10 bouts of WBV (frequency ranging from 15 to 40 Hz, Amplitude 1.2 mm with linear vibration) in the dynamic partial squat position while isometrically contracting quadriceps muscles during the vibration period, keeping knees and hips slightly flexed (20°) with 1 minute rest in between each bout for three days a week for 8 weeks. Control group will be made to perform 10 repetitions of similar dynamic partial squats with same position and duration with vibration platform turned off. Both groups will perform upper and lower limb active exercises against gravity with 10 repetitions for all movements on each joint with 2 minutes rest in between.

Main outcome variables
Skeletal Muscle Mass Index, Muscle strength, Physical performance, Functional mobility, Fall risk, Quality of life, Inflammatory markers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230304057612N1**
Registration date: **2023-04-26, 1402/02/06**
Registration timing: **prospective**

Last update: **2023-04-26, 1402/02/06**
Update count: **0**

Registration date
2023-04-26, 1402/02/06

Registrant information

Name
Shafaq Altaf

Name of organization / entity

Country
Pakistan

Phone
+92 343 5020507

Email address
sh-altaf@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-21, 1402/02/31

Expected recruitment end date
2024-05-20, 1403/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of long-term effects of active range of motion exercises with and without whole-body vibration on skeletal muscle index and physical performance in elderly population with sarcopenia

Public title
Long-Term Effects of Whole-Body Vibration on Sarcopenia in Geriatric Population

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Elderly aged 60 years and above Participants who meet sarcopenia diagnostic criteria based on the EWGSOP2 algorithm for case-finding and diagnosis with Skeletal Muscle Index (SMI) <7.0 kg/m2 and <5.5 kg/m2 for males and females, respectively Negative Romberg's sign Participants who are willing to comply with the study protocol and give informed consent in writing

Exclusion criteria:
Participants who meet “severe” sarcopenia diagnostic criteria based on the EWGSOP2 algorithm for case-finding and diagnosis with a score of ≤8 on Short Physical Performance Battery (SPPB) Presence of any neuromuscular, autoimmune, or infectious diseases Participants with Total Hip Replacement, Total Knee Replacement and any other lower limb implants Participants unable to flex the knee joints to 90° or having pain in their knees or ankles due to any problem such as arthritic changes Participants with any critical cognitive (Mini–Mental State Examination, MMSE score < 23) or physical dysfunctions that may interfere with the test or training procedures Participants with cardiovascular and/or pulmonary diseases, which can get aggravated after exercise Participants who are taking drugs that can affect the neuromuscular system Participants who are osteoporotic with T-score < -2.5 on DEXA at the lumbar spine/ femoral neck/distal third of the radius

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
A stratified block randomization method will be used using "Random Allocation Software", to achieve balance among groups. For this purpose, there are random blocks with a block size of 4 and an allocation ratio of 1 male to 1 female. After this step, a simple randomization procedure (flipping a coin) will be used to assign the participants within each block to one of the experimental or control groups. Therefore, there will be 4 groups with equal sizes.

Blinding (investigator's opinion)
Single blinded

Blinding description
The assessor will be blinded to the participants’ allocation before intervention and posttest measures obtained after intervention. The patients will be unaware of which group they are allocated to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation, Tehran University of

Street address
Building no. 1, North Door of University, Poursina street, Ghods St, Enghelab Avenue

City
Tehran

Province
Tehran

Postal code
1417755354

Approval date
2023-02-01, 1401/11/12

Ethics committee reference number
IR.TUMS.FNM.REC.1401.171

Health conditions studied

1

Description of health condition studied
Sarcopenia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Skeletal Muscle Index (SMI)

Timepoint
before intervention, after intervention and 8 weeks post termination of intervention

Method of measurement
Dual-energy X-ray absorptiometry (DEXA) will be carried out for each participant by the same technician. All assessments will be performed at the same time in the

day around 10 a.m. to 12 noon.

2

Description
Muscle strength
Timepoint
before intervention, after intervention and 8 weeks post termination of intervention
Method of measurement
Dynamometer for the hand grip strength and knee strength will be used. For measuring hand grip strength, participant will be asked to squeeze the handle of dynamometer as strongly as possible while three readings will be noted in kilograms from the alternate hand to relax the other hand. After three trials, the highest value of the 3 repetitions will be considered for each hand separately. For measuring maximal isometric strength of knee extensors, the participants will be instructed to sit with their hips and knees at 90 degrees flexion, legs perpendicular to the floor and the feet not touching the ground. The dynamometer will be placed just proximal to the ankle on the front leg. A high density foam pad may be placed between the dynamometer's force pad and the subjects' leg for comfort and to protect subjects' skin. During testing, the subjects will be instructed to contract maximally and to sustain the maximal voluntary contraction for 5 seconds. The highest value of the 3 measurements will be considered.

3

Description
Physical Performance
Timepoint
before intervention, after intervention and 8 weeks post termination of intervention
Method of measurement
Mini Physical Performance Test will be used to measure balance, strength and mobility. It has 4 components: picking up a penny from floor, a timed 50-feet walk, chair rises (5 times) and a progressive Romberg test. Higher scores indicate better performance.

4

Description
Functional mobility
Timepoint
before intervention, after intervention and 8 weeks post termination of intervention
Method of measurement
Timed Up and Go (TUG) will be administered to assess the changes in the functional mobility of the participant's walking. Measuring tape, chair with arm rest, tape to mark the ground and stopwatch will be used in this test. A 3-meter walkway will be measured by the tape. On one end, a chair would be placed facing down the walkway with front legs as the start point of the 3-meter distance. On the other end, a cone will be placed to serve as a marker. The participants will sit on a chair with their back against the back rest preparing for the test. The participant would be signaled to stand up, walk to the marker, turn around once reached to the marker in order to return to the chair and sit again. The time required by the participant to complete the test will be measured. An older adult who would take more than and equal to 12 seconds to complete TUG test will be at risk of falling.

5

Description
Fall risk
Timepoint
before intervention, after intervention and 8 weeks post termination of intervention
Method of measurement
Falls Efficacy Scale-International which is a short, easy to administer tool that measures level of concern about falling during social and physical activities inside and outside the home whether or not the person usually does the activity. The level of concern is measured on a four-point Likert scale (1=not at all concerned to 4=very concerned) with score of 16 denoting no concern about falling while score of 64 denotes severe concern about falling.

Secondary outcomes

1

Description
Quality of life
Timepoint
before intervention, after intervention and 8 weeks post termination of intervention
Method of measurement
SarQoL questionnaire which is a self-administered questionnaire comprising of 55 items and 22 questions and is organized into 7 domains of health related quality of life (QOL) including Physical and Mental Health, Locomotion, Body composition, Functionality, Activities of daily living, Leisure activities and Fears. Each domain is scored from 0 (worst QOL) to 100 (best QOL) and overall score is calculated.

2

Description
Inflammatory markers
Timepoint
before intervention, after intervention and 8 weeks post termination of intervention
Method of measurement
Plasma levels will be assessed for each participant in the pathologic lab through blood sample obtained from antecubital vein between 8 a.m. to 10 a.m.

Intervention groups

1

Description
Intervention group: It will contain subgroups of an equal number of males and females. This group will receive 10

bouts of WBV with frequency progressively increasing from 15 to 40 Hz (15Hz for 1st and 2nd week, 20Hz for 3rd and 4th week, 30Hz for 5th and 6th week, 40Hz for 7th and 8th week) and Amplitude 1.2 mm with linear vibration in the dynamic partial squat position while isometrically contracting quadriceps muscles during each vibration period (60 seconds), keeping knees and hips slightly flexed (20°) with 1 minute rest in between each bout for three days a week for 8 weeks. During treatment, participants will be made to hold hand railing under supervision of a trained physical therapist. Additionally, they will perform upper and lower limb active exercises against gravity with 10 repetitions for all movements on each joint with 2 minutes rest in between.

Category

Rehabilitation

2

Description

Control group: It will contain subgroups of an equal number of males and females. Control group will be made to perform 10 repetitions of similar dynamic partial squats with same position (knees and hips 20° flexed while isometrically contracting quadriceps muscles) and duration (60 seconds followed by 1-minute rest in between each repetition), three times a week for 8 weeks as in intervention group with vibration platform turned off. During treatment, participants will be made to hold hand railing under supervision of a trained physical therapist. Additionally, they will perform upper and lower limb active exercises against gravity with 10 repetitions for all movements on each joint with 2 minutes rest in between.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Physical Therapy, National Institute of Rehabilitation Medicine

Full name of responsible person

Dr. Vinod Kumar

Street address

Street no. 9, Sector G-8/2, Islamabad, Pakistan

City

Islamabad

Postal code

44080

Phone

+92 333 2097267

Email

dr.vinod.sawlani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi - Vice President of Research and Technology

Street address

Deputy of Research, 6th floor, Tehran University of Medical Sciences, Next to Ghods street, Keshavaez Boulvard

City

Tehran

Province

Tehran

Postal code

1417755354

Phone

+98 919 588 9548

Email

kmalmir@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shafaq Altaf

Position

PhD (Physical therapy) Candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

House 64, Street 59, I-8/3, Islamabad

City

Islamabad

Province

Islamabad Capital Territory

Postal code

44000

Phone

+92 343 5020507

Email

shafaq.altaf.shah@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Kazem Malmir

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, No. 336, Next to Safialishah Street, Piche Shemiran, Enghelab Avenue

City

Tehran

Province

Tehran

Postal code

1148965111

Phone

+98 919 588 9548

Email

kmalmir@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shafaq Altaf

Position

PhD (Physical Therapy) Candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

House 64, Street 59, Sector I-8/3

City

Islamabad

Province

Islamabad Capital Territory

Postal code

44000

Phone

+92 343 5020507

Email

shafaq.altaf.shah@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Sharing IPD is of no use for our study. We should consider the whole sample size.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The results of the primary outcome measure will be shared

When the data will become available and for how long

The data will be available 2 months after publication

To whom data/document is available

The results will be available for physiotherapists and people working in academic institutions

Under which criteria data/document could be used

People can use the data only for rehabilitative purposes

From where data/document is obtainable

Ms. Shafaq Altaf will be in-charge of communication via email: shafaq.altaf.shah@gmail.com

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

After receiving such request and its purpose, we will respond within one month

Comments