Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

study effect of whole body vibration on arthrogenic muscle inhibition of quadriceps muscle in knee osteoarthritis patients

Protocol summary

Study aim
Determine the effectiveness of using whole-body vibration training in reducing arthrogenic inhibition, increasing quadriceps muscle strength, improving pain, improving function, improving balance and improving quality of life in patients with knee osteoarthritis

Design
Clinical trials with intervention, placebo and control groups, double-blind, randomized tables were used for randomization.

Settings and conduct
Location: Faculty of Rehabilitation Sciences, Shahid Beheshti University Blinded: Participants, Analyzer, Variable Tester

Participants/Inclusion and exclusion criteria
Criteria for entering the study: • People with primary osteoarthritis of the knee with grades 2 and 3 based on Kellgren and Lawrence criteria • People with chronic knee pain (having pain in the knee or around the knee most of the time, having pain in the knee in the last year) • Age range 30 to 60 years • no participation in reinforcement sports programs for at least the last 6 months • BMI 22 to 30. • Have at least 10% arthrogenic inhibition in the quadriceps muscle in the affected knee. - Criteria for not entering the study: • Severe cardiovascular disease that prevents exercise. • Drug use. • Perform total knee arthroplasty or any other surgery on the lower limbs • Existence of pain with intensity above 5 based on a visual scale of pain during the study • History of knee surgery, rheumatic or infectious diseases of the knee and cancer • Secondary osteoarthritis

Intervention groups
the intervention group receives 10 session vibration therapy with specific settings, the placebo group receives 10 session vibration therapy while the device is off and makes no vibration. at the beginning of each session, all three groups including intervention,placebo and control group recieves routine knee OA physiotherapy.

Main outcome variables
arthrogenic muscle inhibition, muscle strength, pain, function, quality of life, balance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200203046360N1**
Registration date: **2020-05-30, 1399/03/10**
Registration timing: **prospective**

Last update: **2020-05-30, 1399/03/10**
Update count: **0**

Registration date
2020-05-30, 1399/03/10

Registrant information

Name
Mohadeseh Kazemi Fard

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7756 1721

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-09, 1399/03/20

Expected recruitment end date
2020-07-10, 1399/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
study effect of whole body vibration on arthrogenic muscle inhibition of quadriceps muscle in knee osteoarthritis patients

Public title
effect of whole body vibration on muscle inhibition
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with primary knee osteoarthritis in grade2 or 3 based on kellgren and lawrence criteria patients with chronic knee pain (feeling pain in knee or around of it in most of the time, feeling pain in knee for recent year) age range between 30 and 60 no participant in strengthening program from 6 month ago BMI between 22 and 30 having at least 10% arthrogenic muscle inhibition in quadriceps muscle of affected knee
Exclusion criteria:
severe cardiovascular disease which prevents exercising drug addiction total knee arthroplasty or any other surgery on lower limb pain score more than 5 based on VAS during study knee surgery history , rheumatoid disease or septic knee , cancer secondary osteoarthritis
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
First, when the sampling is done in a simple and accessible way, each sample is given a specific code, then each code is written on a piece of paper and the papers are poured into a container, the number of samples of each group is drawn and The number of papers randomly leaves the container.
Blinding (investigator's opinion)
Double blinded
Blinding description
Keeping participants blind so that patients in the intervention group are visited on even days and the control group is visited on individual days, and each group is unaware of the existence of the other group. Keeping blind variables assessor in such a way that at the time of testing the variables, the assessor is unaware of the type of group therapy and only measured the variables in all participants. Keeping the data analyst blind so that he is unaware of each patient's treatment group at the time of reviewing and analyzing the data, and each patient is introduced to the analyzer with only one identifier code.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of shahid behshti medical university
Street address
next to Ayatollah Taleghani Hospital, Shahid Arabi St., Yemen St., Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2020-01-26, 1398/11/06
Ethics committee reference number
IR.SBMU.RETECH.REC.1398.715

Health conditions studied

1

Description of health condition studied
knee osteoarthritis
ICD-10 code
M15.0
ICD-10 code description
Primary generalized (osteo)arthritis

Primary outcomes

1

Description
arthrogenic muscle inhibition of quadriceps
Timepoint
before any intervention, after first session, end of ten session , one month follow up
Method of measurement
quantitative measurement using digital dianamometer

2

Description
maximal voluntary isometric contraction

Timepoint
before any intervention, after the first session, end of ten-session, one month follow up
Method of measurement
quantitative measurement of muscle strength using digital dinamometer

3

Description
pain
Timepoint
before any intervention, after the first session, end of ten-session, one month follow up
Method of measurement
using VAS

4

Description
function
Timepoint
before any intervention, after the first session, end of ten-session, one month follow up
Method of measurement
using 6 minute waking test

5

Description
balance
Timepoint
before any intervention, after the first session, end of ten-session, one month follow up
Method of measurement
using berg balance scale

6

Description
quality of life
Timepoint
before any intervention, after the first session, end of ten-session, one month follow up
Method of measurement
using WHO-QOL brief questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: whole-body vibration group Vibration frequency: Hz 30/ Vibration amplitude: mm 4 (peak to peak)/ Vibration type: Vertical vibration/ Vibration acceleration: g8.24/ Exercise position: standing, with 30 degrees of flexion, without socks and shoes/ exercise duration: 30 seconds/ Rest duration Between Each Exercise: 60 Seconds/ Number of repetitions in each set: 4 times/ Number of sets: 2 to 4 sets (first, second and third sessions 2 sets / fourth, fifth and sixth sessions 3 sets / seventh, eighth, ninth and tenth sessions 4 sets)/ Rest duration between each set: 5 minutes Routine physiotherapy treatment includes: 20-minute electrical stimulation / 5-minute ultrasound therapy and quadriceps muscle strengthening exercises
Category
Rehabilitation

2

Description
Intervention group: placebo Use the whole body vibration device for 4 sets of 30 seconds per set and rest for 60 seconds between each set while the device is off and has no vibration. Routine physiotherapy treatment includes: 20-minute electrical stimulation / 5-minute ultrasound therapy and quadriceps muscle strengthening exercises
Category
Rehabilitation

3

Description
Control group: control Routine physiotherapy treatment includes: 20-minute electrical stimulation / 5-minute ultrasound therapy and quadriceps muscle strengthening exercises
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Rehabilitation faculaty of Shahid Behshti Medical science
Full name of responsible person
Mohadeseh Kazemi Fard
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SBMU School of Rehabilitation Sciences, Damavand St, Across from Bu Ali Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
5th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

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Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Khosro Khademi-Kalantari

Position
Proffesor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Person responsible for scientific inquiries

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Position
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Other areas of specialty/work
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Person responsible for updating data

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Position
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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

may share the main results of the study

When the data will become available and for how long

after the end of the study in1399

To whom data/document is available

for the academic researchers

Under which criteria data/document could be used

analysis results in each group are able to represent as tables and graphs

From where data/document is obtainable

The main presenter, Dr. Khosrow Khademi Kalantari, Professor, Department of Physiotherapy, Faculty of Rehabilitation, Shahid Beheshti University of Medical Sciences

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

After submitting a written request to the main executor and stating the reason for the data request, if the main executor is approved, the data file will be provided as needed.

Comments