

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effect of whole body vibration training, on the lower limb muscles' electromyography and timing of activation in patients with knee osteoarthritis during functional activity

Protocol summary

Study aim

The aim of this study was to investigate the effect of whole body vibration on electromyographic changes and timing of lower limb muscle activity in patients with knee osteoarthritis during functional activity.

Design

68 patients with osteoarthritis of the knee participate in this single blind study, which is randomly divided into two groups of intervention and control using four random blocks.

Settings and conduct

Volunteer participants with osteoarthritis of the knee referred to the Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences are included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria in this study are complete satisfaction with participation in this study, age between 55 and 75, grade 2 and 3 knee osteoarthritis, visual analogue scale < 4. Exclusion criteria include acute symptomatic osteoarthritis, previous or concomitant injury to the knee and other lower limb joints, history of serious trauma, surgery and arthroplasty of the knee and other lower limb joints, history of knee intra-articular injection of hyaluronic acid or steroid in the last 6 months, history of medical problems and chronic diseases, history of newly repaired fractures and bone implants, having a pacemaker under medical treatment, incomplete treatment and evaluation, whole body vibration training contraindication and a whole body vibration intolerance.

Intervention groups

The control group will receive routine physiotherapy including TENS, Continuous US, hot packs and strengthening exercises three days a week for 4 weeks. In addition to routine physiotherapy, the intervention group will receive WBVT therapy sessions 3 days a week for 4 weeks at a frequency of 30 Hz and a 2 mm

amplitude.

Main outcome variables

Active time, onset time and peak time during the static phase of the gate and RMS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150602022539N11**

Registration date: **2021-10-22, 1400/07/30**

Registration timing: **prospective**

Last update: **2021-10-22, 1400/07/30**

Update count: **0**

Registration date

2021-10-22, 1400/07/30

Registrant information

Name

Ziaeddin Safavi Farokhi

Name of organization / entity

Semnan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of whole body vibration training, on the lower limb muscles' electromyography and timing of activation in patients with knee osteoarthritis during functional activity

Public title

Effect of whole body vibration training, on the lower limb muscles' electromyography and timing of activation in patients with knee osteoarthritis during functional activity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Complete satisfaction to participate in this study Age between 55 and 75 years Kellgren-Lawrence grade two and three knee osteoarthritis in plain imaging VAS < 4

Exclusion criteria:

Acute symptomatic OA Previous or concomitant injury on the knee and other lower extremity joints Previous history of serious knee trauma, surgery and arthroplasty History of knee intra-articular injection of hyaluronic acid or steroid in the last 6 months History of medical problems such as cardiopulmonary disease, neurologic disease, malignant disease, chronic disease such as diabetes History of newly repaired fracture and bone implants Having a pace maker Taking any medication Incomplete treatment and assessment History of WBVT contraindications (epilepsy, vertigo, uncontrolled hypertension, acute hernia, serious cardiovascular disease, pacemaker, acute thrombosis, tumors, recent surgery) WBVT intolerance

Age

From **55 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Permuted block randomization will be used for randomization, which includes 4 blocks (2 participants in the intervention group and 2 participants in the control group). Random allocation software is also used for randomization tools. In order to create an allocation concealment, each random sequence created is recorded on a card and the cards are placed in sealed opaque envelopes, respectively. In order to maintain a

random sequence, the envelopes are numbered in the same way on the outer surface. At the beginning of the registration of participants, according to the order of arrival, one of the envelopes is opened in order and the assigned group of that participant is identified.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, blindness will be done in the participants. Participants from both groups will be admitted at different times for evaluation and intervention and will not be aware of the type of intervention of the other group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan, km 5 of Damghan road, Semnan University of Medical Sciences

City

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Province

Semnan

Postal code

3519899951

Approval date

2021-10-04, 1400/07/12

Ethics committee reference number

IR.SEMUMS.REC.1400.155

Health conditions studied**1****Description of health condition studied**

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes**1****Description**

Onset time of muscle activity during stance phase of a

gait cycle

Timepoint

Before and after one month of intervention

Method of measurement

Surface EMG system and force plate

2

Description

RMS of muscle activity during stance phase of a gait cycle

Timepoint

Before and after one month of intervention

Method of measurement

Surface EMG system

Secondary outcomes

1

Description

Active time of muscle activity during stance phase of a gait cycle

Timepoint

Before and after one month of intervention

Method of measurement

Surface EMG system and force plate

2

Description

Peak time of muscle activity during stance phase of a gait cycle

Timepoint

Before and after one month of intervention

Method of measurement

Surface EMG system and force plate

Intervention groups

1

Description

Control group: routine physiotherapy including TENS, Continuous US, hot packs and strengthening exercises three days a week for 4 weeks

Category

Rehabilitation

2

Description

Intervention group: routine physiotherapy including TENS, Continuous US, hot packs and strengthening exercises and WBVT exercises with 3 mm amplitude and 30 Hz frequency three days a week for 4 weeks

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Research Center of Semnan
University of Medical Sciences

Full name of responsible person

Ziaeddin safavi farrokhi

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Semnan, Mashahir Square, in front of the Red
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research and Technology, Semnan
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

Semnan University of Medical Sciences

Full name of responsible person

Ziaeddin Safavi Farrokhi

Position

PhD, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Other areas of specialty/work

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Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available