Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The study of the Whole Body Vibration Therapy effects on Pain , Knee Range of Motion, Functional Activities, Electromyography Muscles Activity of the Lower Limbs and Postural Stability of Patients with Knee Osteoarthritis.

Protocol summary

Summary

Objectives: The purpose of this study will be to analyze the short term effects of Whole body vibration therapy on pain, knee range of motion, electromyographic (EMG) root mean square (RMS) response of some lower limb muscles and physical function in patients with knee osteoarthritis Design : A single blinded randomized clinical trial. Setting and conduct :T he patients will be randomly divided into three groups: (1) WBVT group receiving vibration therapy, (2)exercise practice at home (3)placebo .The patients will be received the interventions related to their group for 1 month . Participants including major eligibility criteria: Inclusion criteria - Knee OA, between 55-75 years old, no previous or concomitant injury on the knee and other lower extremity joints, no previous history of serious knee trauma and surgery and arthroplasty, no history of knee intra-articular injection of hyaluronic acid or steroid in the last 6 months, no history of surgery or traumatic injuries to the lower limbs, no history of medical problems such as cardiopulmonary diseases, no history of newly repaired fracture and bone implants, no pacemaker and no history of WBVT contraindications for participants of the WBVT group. Exclusion criteria- Patient's willing to leave the study, incomplete treatment and assessment , WBVT intolerance for the WBVT group and doing extra exercises out of the study design . Intervention: 1. Whole body vibration therapy for WBVT group. 2. Placebo Whole body vibration therapy for placebo group. 3. Exercise therapy for exercise practice at home group. Main outcome measures: Pain intensity, Knee range of motion, EMG activity (RMS) the muscles of lower limb, Balance and postural stability , Physical function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601171637N5**
Registration date: **2016-04-03, 1395/01/15**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-03, 1395/01/15

Registrant information

Name
Sedighe Kahrizi
Name of organization / entity
Tarbiat Modares University
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Recruitment status

Recruitment complete

Funding source

Tarbiat Modares University

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The study of the Whole Body Vibration Therapy effects on Pain , Knee Range of Motion, Functional Activities, Electromyography Muscles Activity of the Lower Limbs and Postural Stability of Patients with Knee Osteoarthritis.

Public title
The study of the whole body vibration therapy effects on the patients with knee osteoarthritis.

Purpose
Treatment

Inclusion/Exclusion criteria
The inclusion criteria: Knee OA with Kellgren–Lawrence grade II and III in simple X-ray; between 55-75 years old; no previous or concomitant injury on the knee and other lower extremity joints; no previous history of serious knee trauma, surgery and arthroplasty; no history of knee intra-articular injection of hyaluronic acid or steroid in the last 6 months; no history of surgery or traumatic injuries to the lower limbs; no history of medical problems such as cardiopulmonary diseases, neurologic diseases, malignant diseases, chronic diseases such as diabetes; no history of newly repaired fracture and bone implants; no pacemaker and no history of WBVT contraindications for participants of the WBVT group; The exclusion criteria: Any systemic disorder in the body, according to the patient and physician; taking any medication according to the patient; incomplete treatment and assessment; WBVT intolerance for the WBVT group;

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The patients were randomly allocated to three groups: WBVT, placebo and control . It is worth noting that patients are not aware of the different treatment groups and were treated at different times.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethical Committee of Medicine School-Tarbiat Modares University

Street address
Physiotherapy Department,Medicine school,Jalal Al Ahmad Highway.

City
Tehran

Postal code

Approval date
2014-09-23, 1393/07/01

Ethics committee reference number
52.2521

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis

ICD-10 code
M 17

ICD-10 code description
Other primary gonarthrosis

Primary outcomes

1

Description
Pain

Timepoint
Pre and post intervention

Method of measurement
Visual Analogue Scale for pain(100 mm Ruler)

2

Description
Knee Range of Motion

Timepoint
Pre and post intervention

Method of measurement
Goniometery in degree

3

Description
Time up & Go test

Timepoint
Pre and post intervention

Method of measurement
Chronometer (sec)

4

Description
6 minute walk test
Timepoint
Pre and post intervention
Method of measurement
Meter

5

Description
Electromyographic (EMG) root mean square (RMS) response of some lower limb muscles during maximum voluntary isometric contraction
Timepoint
Pre and post intervention
Method of measurement
Electromygraphy

6

Description
Overall Sway Index
Timepoint
Pre and post intervention
Method of measurement
Biodex Balance System

7

Description
Antroposterior Sway Index
Timepoint
Pre and post intervention
Method of measurement
Biodex Balance System

8

Description
Medilateral Sway Index
Timepoint
Pre and post intervention
Method of measurement
Biodex Balance System

Secondary outcomes

1

Description
Anteroposterior Sway
Timepoint
pre andp post intervention
Method of measurement
Forceplate

2

Description
Sway Average Velocity
Timepoint
pre andp post intervention
Method of measurement
Forceplate

3

Description
Mediolateral Sway
Timepoint
pre andp post intervention
Method of measurement
Forceplate

Intervention groups

1

Description
The whole body vibration training group will do their intervention on a vibration platform .The WBVT programme will be done on the Fitvibe vertical vibration platform with amplitude of 3 mm and frequency of 30 Hz. The patients will ask to stand barefoot on the platform with a 30 degree knee flexion during training. The vibration training will consist of two set with three repetitions of one-minute WBVT and one-minute rest between repetitions and five minute rest between the sets during the first week to avoid patients' muscles fatigue. Every week a set will be added to the WBVT program, so that the WBVT in the fourth week will be consisted of five sets. The patients will be allowed to sit down on a chair for the rest between the sets.
Category
Rehabilitation

2

Description
The patient in placebo group will do their intervention on a vibration platform as WBVT group while the vibration system is off and does not transmit any vibration to the patient's feet while standing in semi squat position. Their protocol will be similar to the WBVT group but without receiving vibration. The reason for designing a placebo group in this study is to evaluate the placebo and psychological effects of WBVT.
Category
Rehabilitation

3

Description
The practice at home group will be educated to do two exercises in three set with ten repetitions and a five-second hold for each exercise and a five-second pause. The exercise program of the group will consist of static contractions of quadriceps muscles and SLR which will be done twice a day at home. The exercise therapy course is also four weeks in this group
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Physiotherapy Clinic- Physiotherapy Department-Medicine School

Full name of responsible person
Sadighe Kahrizi

Street address
Medicine School-Tarbiat Modares University-Jalal Al Ahmad Highway

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research-Tarbiat Modares University

Full name of responsible person
Dr. Yaghoub Fathollahi

Street address
Jalal Al Ahmad Highway , Pole Nasr ,Tarbiat Modares University, Centeral building, Third Floor , PO Box 14115-318.

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research-Tarbiat Modares University

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tarbiat Modares University

Full name of responsible person
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Position
PhD-candidate of physical therapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty