

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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 : The 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8288 4511

##### Email address

kahrizis@modares.ac.ir

##### 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**

Goniometry 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**

Electromyography

#### 6

**Description**

Overall Sway Index

**Timepoint**

Pre and post intervention

**Method of measurement**

Biodex Balance System

#### 7

**Description**

Anteroposterior Sway Index

**Timepoint**

Pre and post intervention

**Method of measurement**

Biodex Balance System

#### 8

**Description**

Medialateral 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

**City**

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, Central 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**

Ebrahim Abbasi

**Position**

PhD-candidate of physical therapy

**Other areas of specialty/work****Street address**

Tarbiat Modares University, Jalal Ale Ahmad Highway,  
P.O.Box: 14115-318, Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 8288 4511

**Fax**

+98 21 8288 4511

**Email**

ebiabasi@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Sadighe Kahrizi

**Position**

PhD- Assistant professor

**Other areas of specialty/work****Street address**

Physiotherapy department, Tarbiat Modares  
University, Jalal Ale Ahmad Highway, P.O.Box:  
14115-318, Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 8288 4511

**Fax**

+98 21 8288 4511

**Email**

kahrizis@modares.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Sadighe Kahrizi

**Position**

PhD - Assistant professor

**Other areas of specialty/work****Street address**

Physiotherapy department, Tarbiat Modares  
University, Jalal Ale Ahmad Highway, P.O.Box:  
14115-318, Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 8288 4511

**Fax**

+98 21 8288 4511

**Email**

kahrizis@modares.ac.ir

**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*