

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Effects of therapeutic ultrasound on postural sway indices in women with knee osteoarthritis

#### Protocol summary

##### Study aim

Effects of the pulsed ultrasound on postural sway indices in women with knee osteoarthritis

##### Design

Randomized clinical trial, no blinding Patients with knee osteoarthritis were randomly assigned to one of the three intervention groups by using sealed envelope

##### Settings and conduct

After initial evaluation and check the conditions of the inclusion and exclusion criteria by rheumatologist, patients were referred to Tarbiat Modares University for evaluation and interventional therapy. The venue of the research was in No. 2 Faculty of Medicine, Tarbiat Modares University, Tehran.

##### Participants/Inclusion and exclusion criteria

Primary symptomatic knee osteoarthritis for at least 6 months Not having any contraindications for treatment with ultrasound (like cancer, wound, ...) Should not present neuromuscular, musculoskeletal, chronic inflammatory disorders, diabetes or any other conditions that could affect the balance of the patients Not having osteoporosis

##### Intervention groups

1) Placebo ultrasound plus exercise therapy group: 10 sessions of sham ultrasound with isotonic and isometric exercises of the lower limbs 2) Ultrasound group: 10 sessions of treatment with pulsed ultrasound 3) Ultrasound plus exercise therapy group: 10 sessions of treatment with pulsed ultrasound with performing isotonic and isometric exercises of the lower extremities 4) Healthy subjects group: Just make initial evaluations for comparison with patient groups

##### Main outcome variables

Center of Pressure Path Length Center of Pressure displacement range Center of Pressure displacement velocity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161015030306N2**

Registration date: **2018-03-19, 1396/12/28**

Registration timing: **retrospective**

Last update: **2018-03-19, 1396/12/28**

Update count: **0**

##### Registration date

2018-03-19, 1396/12/28

##### Registrant information

##### Name

seyed mehdi mohsenipour

##### Name of organization / entity

tarbiat modares university

##### Country

Iran (Islamic Republic of)

##### Phone

+98 82880021

##### Email address

m.mohsenipour@modares.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

tarbiat modares university

##### Expected recruitment start date

2016-04-03, 1395/01/15

##### Expected recruitment end date

2016-07-22, 1395/05/01

##### Actual recruitment start date

2016-04-03, 1395/01/15

##### Actual recruitment end date

2016-09-22, 1395/07/01

##### Trial completion date

empty

## Scientific title

Effects of therapeutic ultrasound on postural sway indices in women with knee osteoarthritis

## Public title

Effects of therapeutic pulsed ultrasound on balance in women with knee osteoarthritis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Primary symptomatic knee osteoarthritis for at least 6 months Women between the ages of 40 and 73 years No other treatments for 6 months prior to the study

### Exclusion criteria:

No contraindications for treatment with ultrasound (like cancer, wound, ...) Subjects should not present serious neurologic and systemic diseases, musculoskeletal or chronic inflammatory disorders, diabetes or any other conditions that could influence the balance of the patients Not having osteoporosis

## Age

From **40 years** old to **73 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **38**

Actual sample size reached: **38**

## Randomization (investigator's opinion)

N/A

## Randomization description

Randomization with sealed envelopes. subjects pick up one envelope and enter one of the three groups of intervention by chance.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tarbiat Modares University

##### Street address

Tarbiat Modares University, Nasr, Jalal e al e ahmad, Tehran

##### City

Tehran

## Province

Tehran

## Postal code

1411713116

## Approval date

2016-03-05, 1394/12/15

## Ethics committee reference number

IR.TMU.REC.1394.249

## Health conditions studied

### 1

#### Description of health condition studied

Knee osteoarthritis

#### ICD-10 code

M15-M19

#### ICD-10 code description

In this block the term osteoarthritis is used as a synonym for arthrosis or osteoarthrosis. The term primary has been used with its customary clinical meaning of no underlying or determining condition identified.

## Primary outcomes

### 1

#### Description

Center of Pressure path length, Center of Pressure displacement Range, Center of Pressure displacement velocity

#### Timepoint

Before intervention, 2 till 4 days after intervention

#### Method of measurement

Force plate

## Secondary outcomes

### 1

#### Description

Pain, functional balance status

#### Timepoint

Before intervention. 2 till 4 days after intervention

#### Method of measurement

Visual Analogue Scale questionnaire, WOMAC questionnaire, Lequesne questionnaire, Timed Up and Go Test, 6 Minute Walk Test

## Intervention groups

### 1

#### Description

Placebo ultrasound plus exercise therapy group: Advise plus off ultrasound plus exercise therapy. Ultrasound group: Advise plus pulsed ultrasound. Ultrasound plus exercise therapy group: Advise plus pulsed ultrasound plus exercise therapy. Healthy subjects group

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Baqiatallah hospital

**Full name of responsible person**

Dr Nooshin Bayat, Rheumatologist, Professor of Baqiatallah University

**Street address**

Sheikh bahaei st, Mollasadra st, Vanak square

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۵۹۱۵۳۷۱

**Phone**

+98 21 8805 0436

**Email**

Nobayat@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Vice head of research

**Street address**

No. 3 Faculty of Medicine, Tarbiat Modares University, Jalal e Al e Ahmad, Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1411713116

**Phone**

+98 21 8288 2009

**Fax**

+98 21 8800 6544

**Email**

Res@modares.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tarbiat Modares University

**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**

Tarbiat Modares University

**Full name of responsible person**

Roya Ravanbod

**Position**

Ph.D of Physical Therapy, Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

No 3 Faculty of medicine, Tarbiat Modares University, Jalal e Al e Ahmad

**City**

Tehran

**Province**

Tehran

**Postal code**

14115-111

**Phone**

+98 21 8288 3287

**Fax****Email**

rravanbod@hotmail.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Seyed Mehdi Mohsenipour

**Position**

Msc student of physical therapy

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Roya Ravanbod

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Ph.D of physical therapy, Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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1411713116

**Phone**

+98 21 8288 3287

**Fax**

**Email**

rravanbod@hotmail.com

**Web page address**

## 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**

If the data would be necessary for a research, only after evaluation and permission from the vice head of research of Tarbiat Modares university

**Study Protocol**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

Data of the study includes postural sway indices, changes in pain and functional status. The data of major outcome is shareable and personal informations are not shareable.

**When the data will become available and for how long**

Access after the thesis defence

**To whom data/document is available**

Physiotherapy colleagues and other researchers

**Under which criteria data/document could be used**

For research and treatment purposes

**From where data/document is obtainable**

1) Seyed Mehdi Mohsenipour with electronic mail: Mohsenipour@hotmail.com 2) Roya Ravanbod with electronic mail: rravanbod@modares.ac.ir

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

The applicant can access the data in one week by sending email to any of top electronic mails.

**Comments**