

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### TRX training vs. aquatic therapy for patients with kneeosteoarthritis

#### Protocol summary

##### Study aim

The effect of water treatment therapy and TRX training on pain and function of patients with knee osteoarthritis.

##### Design

120 patient were selected to participate in the study. Subjects were randomized by Random Number Generator software then assigned to three groups by sequentially numbered, sealed, opaque envelopes (SNOSE) method. Participants were randomly assigned to one of the TRX training, aquatic therapy and control groups. Considering the drop in the subjects, the groups were reduced to 19 patients in aquatic therapy, 18 patients in TRX and 16 patients in control. Aquatic therapy and TRX were performed for eight weeks, three sessions a week, and each session was 90 minutes.

##### Settings and conduct

Aquatic therapy was done in the water with 32 ° C, 1.5 m the depth of water was. The exercise protocol in water included 10 minutes of walking and stretching exercises for the lower extremity muscles. 30 minutes for lower leg muscles' isometric strengthening exercises, 20 minutes for aerobic exercises, 20 minutes for step and proprioceptive exercises and 10 minutes for cool down. TRX exercises included hip abductors, hip extensors, quadriceps, hamstrings, Core muscles, and ankle flexor / extensors muscles strengthening training.

##### Participants/Inclusion and exclusion criteria

Age 40 years or more, having American College of Rheumatology clinical criteria for knee OA , having primarily internal compartment disease greater than II on the Kellgren and Lawrence radiographic disease severity scale. Exclusion criteria: Age 40> years, stroke, tumors, patients who couldn't walk without assistant equipment, patients with a ban to enter the pool.

##### Intervention groups

Hydrotherapy, TRX, Control

##### Main outcome variables

Balance, Performance indicators: WOMAC, Time Up and Go, 40 m walk tests, up and down 10 steps, Deep knee joint sensation

#### General information

##### Reason for update

The error of the student who registered the dates of IRCT

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181222042070N1**

Registration date: **2019-02-22, 1397/12/03**

Registration timing: **prospective**

Last update: **2024-11-18, 1403/08/28**

Update count: **2**

##### Registration date

2019-02-22, 1397/12/03

##### Registrant information

##### Name

Mahsa Mozafari Kakavandi

##### Name of organization / entity

The university of Razi

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3724 2588

##### Email address

mahsa.mozafari1988@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-01, 1397/10/11

##### Expected recruitment end date

2019-10-15, 1398/07/23

##### Actual recruitment start date

2019-03-01, 1397/12/10

##### Actual recruitment end date

2019-12-30, 1398/10/09

##### Trial completion date

2019-12-30, 1398/10/09

## Scientific title

TRX training vs. aquatic therapy for patients with kneeosteoarthritis

## Public title

TRX training vs. aquatic therapy for patients with kneeosteoarthritis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age 40 years or more, having American College of Rheumatology clinical criteria for knee OA , having primarily internal compartment disease greater than II on the Kellgren and Lawrence radiographic disease severity scale.

### Exclusion criteria:

Age 40> years, stroke, tumors, patients who couldn't walk without assistant equipment, patients with a ban to enter the pool, patients who have received other training or nutritional treatments in the last three months, Patients who had obesity criterion, neuromuscular diseases such as MS and Parkinson's disease, patients who had a history of heart disease, fractures in the lower extremities, pain in the back or thigh, hip osteoarthritis simultaneously, at the waited list for arthroplasty surgery, or do it

## Age

From **40 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **200**

Actual sample size reached: **53**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The subjects were randomized based on Random Number Generator software and then they were assigned to aquatic therapy, TRX and control groups based on allocation concealment by SNOSE method.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, the assessor was unaware of the exercises and interventions assigned to the groups

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kermanshah University of Medical Sciences

##### Street address

Shahid Beheshti Blvd.

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

#### Approval date

2018-12-16, 1397/09/25

#### Ethics committee reference number

IR.KUMS.REC.1397.718

## 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

Balance

#### Timepoint

Before the intervention, two two months later and six months later

#### Method of measurement

Leaf Balance Test: This test consists of 14 equilibrium-performance tests and evaluates various aspects of the daily activities that require maintaining balance. Each test is scored from zero to four, and the whole scale has a total score of 56.

### 2

#### Description

Time up and Go

#### Timepoint

Before the intervention, two two months later and six months later

#### Method of measurement

WOMAC, Time Up and Go, 40 m walk tests, up and down 10 steps.

### 3

#### Description

Deep knee joint sensation

### **Timepoint**

Before the intervention, two two months later and six months later

### **Method of measurement**

To measure the depth of the knee, a method is used to reconstruct the target angle. In this method, the patient is in a sitting position using a universal goniometer to measure angles.

## **Secondary outcomes**

### 1

#### **Description**

pain

#### **Timepoint**

Before intervention, 2 months later, 6 months later

#### **Method of measurement**

Visual Analogue Scale questionnaire

### 2

#### **Description**

Evaluating the quality of life

#### **Timepoint**

Before intervention, 2 months later, 6 months later

#### **Method of measurement**

SF-36 questionnaire

## **Intervention groups**

### 1

#### **Description**

Intervention group: TRX exercises. TRX exercise was also conducted for eight weeks, three sessions per week and 60 minutes each session by the TRX specialist.

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group: Water therapy exercises. Water therapy training was conducted for eight weeks, three sessions a week, and each session is 90 minutes, so that the entire session of the water therapy was 16 sessions, which was completed by a graduate student with a degree in physical education Water therapy was performed.

#### **Category**

Rehabilitation

### 3

#### **Description**

Control group: This group did not receive any training and intervention.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Dr. Shirin Assar's office

##### **Full name of responsible person**

Dr Farzane Gandomi

##### **Street address**

Razi University of Kermanshah

##### **City**

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##### **Province**

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##### **Postal code**

6714414971

##### **Phone**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Razi University of Kermanshah

##### **Full name of responsible person**

Farzane Gandomi

##### **Street address**

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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**

Dr Farzane Gandomi

#### **Proportion provided by this source**

100

#### **Public or private sector**

Private

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Other

## Person responsible for general inquiries

gandomi777@gmail.com

### Contact

**Name of organization / entity**  
Razi University of Kermanshah  
**Full name of responsible person**  
Farzane Gandomi  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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

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

### 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

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

### Data Dictionary

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