# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Oct 2026

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

## Protocol summary

**Study aim**

The effect of water treatment therapy andTRX 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**
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**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.

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**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
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## Sponsors / Funding sources

### 1

**Sponsor**
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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

**Contact**

**Name of organization / entity**
Razi University of Kermanshah

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**Position**
science Committee

**Latest degree**
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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