

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Kermanshah

Province

Kermanshah

Postal code

671414971

Phone

+98 83 3724 2588

Email

gandomi777@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University of Kermanshah

Full name of responsible person

Farzane Gandomi

Street address

Bagh Abrisham

City

Kermanshah

Province

Kermanshah

Postal code

671414971

Phone

+98 83 3427 7605

Email

gandomi777@gmail.com

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
Position
science Committee
Latest degree
Ph.D.
Other areas of specialty/work
Physical Education
Street address
Bagh Abrisham
City
Kermanshah
Province
Kermanshah
Postal code
۶۷۱۴۴۱۴۹۷۱
Phone
+98 83 3427 7605
Email
gandomi777@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Razi University of Kermanshah
Full name of responsible person
Farzane Gandomi
Position
Science Committee
Latest degree
Ph.D.
Other areas of specialty/work
Physical Education
Street address
Bagh Abrisham
City
Kermanshah
Province
Kermanshah
Postal code
۶۷۱۴۴۱۴۹۷۱
Phone
+98 83634277605
Email

Person responsible for updating data

Contact

Name of organization / entity
Razi University of Kermanshah
Full name of responsible person
Mahsa Mozafari
Position
Student
Latest degree
Master
Other areas of specialty/work
Physical Education
Street address
Kasra
City
Kermanshah
Province
Kermanshah
Postal code
۶۷۱۴۴۱۴۹۷۱
Phone
+98 83 3724 2588
Email
mahsa.mozafari1988@yahoo.com

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