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
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
۶۷۱۴۴۱۴۹۷۱
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
۶۷۱۴۴۱۴۹۷۱
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

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

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Farzane Gandomi

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Science Committee

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Physical Education

Street address
Bagh Abrisham

City
Kermanshah

Province
Kermanshah

Postal code
۶۷۱۴۴۱۴۹۷۱

Phone
+98 83634277605

Email
gandomi777@gmail.com

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