

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of hydrotherapy on balance in patients with grade 2 and 3 knee osteoarthritis: A randomized clinical trial

Protocol summary

Study aim

Determining the effect of hydrotherapy on the balance of patients with knee osteoarthritis grade 2 and 3

Design

The study was a randomized double-blind controlled clinical trial. In this study, patients will randomly divide into three groups of hydrotherapy, land based and control.

Settings and conduct

Razmjo Moghadam Physiotherapy Clinic Zahedan Islamic Republic of Iran

Participants/Inclusion and exclusion criteria

(women aged 45 to 65 years) with knee osteoarthritis, grade 2 or grade 3 knee osteoarthritis, can be trained to walk on urban barriers. No history of diseases such as urinary incontinence, open-sore, skin diseases, cardiovascular disease, uncontrolled blood pressure, uncontrolled diabetes, any neurological disease, such as epilepsy, vertigo and vestibular problems, based on the dynamic visual acuity test, Stroke and Parkinson. The patient does not have to use walking accessories like a cane. There is no articular injection in the last three months. There is no traumatic lower extremity surgery, no damage to the knee that has just occurred. No lower extremity replacement, no patient attending any physiotherapy or hydrotherapy program during the last three months. Exit criteria: Reporting the symptoms of the patient during the treatment sessions The patient does not complete the treatment sessions. The patient will use other treatments during the study

Intervention groups

Control group: 12 sessions of routine physiotherapy including: TENS and hot pack, warming stage, stretching exercise, isometric strengthening, concentric and resistance training, and cool down land based group: In addition to routine physiotherapy treatments, they receive a balanced diet Hydrotherapy Group: In addition to routine physiotherapy, they receive a hydrotherapy program that includes: Balancing exercises inside the

water.

Main outcome variables

Balance; risk of falling; pain, disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160531028186N4**

Registration date: **2019-10-09, 1398/07/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-09, 1398/07/17**

Update count: **0**

Registration date

2019-10-09, 1398/07/17

Registrant information

Name

Mohammad Hosseinifar

Name of organization / entity

Zahedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hydrotherapy on balance in patients with grade 2 and 3 knee osteoarthritis: A randomized clinical trial

Public title

The effect of hydrotherapy on balance in patients with grade 2 and 3 knee osteoarthritis: A randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients (women aged 45-65) with osteoarthritis knee grad 2 or 3 knee osteoarthritis, according to Kellgren-Lawrence grade, can be trained to walk on urban obstacles. No history of diseases such as urinary incontinence, open wound, skin diseases, heart disease lung disease, uncontrolled hypertension, uncontrolled diabetes Any neurological disorders, such as epilepsy, dizziness and problems vestibular based on testing dynamic visual acuity, Stroke and Parkinson. The patient is not required to use walking accessories like a cane. There is no articular injection in the last three months. There is no traumatic surgery in the lower extremity. Do not have any damage to the knee that has just occurred.

Exclusion criteria:

Reporting an increase in symptoms by the patient during treatment sessions The patient does not complete the treatment sessions The patient will use other treatments during the study

AgeFrom **45 years** old to **65 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

The randomization method is based on permutation blocks. The randomization unit is an individual. The random number table is used Participants in the study are selected based on simple and accessible sampling. Each person will be selected based on the criteria for entering the study. The placement of people in groups is based on permutation blocks

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients with knee osteoarthritis and data collectors are

kept blind

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Zahedan University of Medical Sciences

Street address

Deputy of Research, Zahedan University of Medical Sciences, Jannat Blvd., Dr. Hesabi Sq

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Zahedan

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Postal code

9816743463

Approval date

2019-07-09, 1398/04/18

Ethics committee reference number

IR.ZAUMS.REC.1398.222

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 and after the period of the interventions

Method of measurement

Biodex system

Secondary outcomes**1****Description**

Pain

Timepoint

Before and after the period of the interventions

Method of measurement

Using Visual Analog Scale (VAS) questionnaire

2**Description**

Risk of falling

Timepoint

Before and after the period of the interventions

Method of measurement

Biodex system

3**Description**

Disability

Timepoint

Before and after the period of the interventions

Method of measurement

WOMAC questionnaire

Intervention groups**1****Description**

The control group received routine physical therapy in 12 sessions three times a week for 4 consecutive weeks, including TENS and Hot Pack (for 20 minutes), a warm-up phase (for 5 minutes), stretching exercises (fifteen Seconds for three to four repetitions) for hamstring muscles, quadriceps, iliosus and planar ankle flexors and slipping the heel on the bed in supine position in order to maintain and increase the range of motion, 10 minutes of isometric, concentric and resistance strengthening exercises (ten seconds Ten repetitions) for hamstring muscles, hip adducts, hip abductors, dorsi flexors and plantar flexors, and last 5 minute cooling phase include: walking and stretching muscles mentioned the warm-up phase

Category

Rehabilitation

2**Description**

Hydrotherapy Group: In addition to routine physiotherapy, the hydrotherapy program (for a maximum of 20 minutes) receive(in 12 sessions three times a week for 4 consecutive weeks), including: Balancing exercises in the water

Category

Rehabilitation

3**Description**

Land base exercise group in addition to routine physiotherapy treatments, they receive a special balance (for a maximum of 20 minutes)(in 12 sessions three times a week for 4 consecutive weeks) on the land

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Razmjo Moghadam Physiotherapy Clinic

Full name of responsible person

Dr.Mohammad Hosseinifar

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Dept. of Physiotherapy, School of Rehabilitation Sciences, Razmejo Moghadam Laboratory, Ayatoallah Kafami St.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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

No

Title of funding source

Vice Chancellor for Research, Zahedan University of Medical Sciences

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**

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hosseinifar

Position

Ph.D in Physiotherapy

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of the data can be shared.

When the data will become available and for how long

6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers and specialists in this field It must be ensured that data will not be misused

From where data/document is obtainable

pt.f_hajmohammadi@zaums.ac.ir
pt.farzaneh24@gmail.com

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

The applicant must clearly and concisely present his / her intention. After about two to four weeks of verification, the data will reach him

Comments