

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 54 3329 1692

##### Email address

fardash\_s@zaums.ac.ir

##### 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

**Age**

From **45 years** old to **65 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target 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

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**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

#### **Street address**

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

#### **City**

Zahedan

#### **Province**

Sistan-va-Balouchestan

#### **Postal code**

64855-98136

#### **Phone**

+98 54 3321 7006

#### **Email**

fardash\_s@zaums.ac.ir

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

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

Zahedan University of Medical Sciences

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

Dr. Noor mohammad Bakhshani

#### **Street address**

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

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+98 54 3329 5796

#### **Email**

nmbakhsha@zaums.ac.ir

#### **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

**Street address**

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

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**Person responsible for scientific 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**

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**Person responsible for updating data****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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**Postal code**

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**Phone**

+98 54 3342 4675

**Email**

fardash\_s@zaums.ac.ir

**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**