Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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.
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
64855-98136
Phone
+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.
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
64855-98136
Phone
+98 54 3342 4675
Email
fardash_s@zaums.ac.ir

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
Physiotherapy
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 3342 4675
Email
fardash_s@zaums.ac.ir

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
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 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