

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

The effect of walking with reverse heel shoes concomitant with routine physiotherapy program on pain, range of motion, stride length, walking speed and disability in patients with knee osteoarthritis

Protocol summary

Study aim

The aim of this study is to consider the effect of walking with reverse heel shoes concomitant with routine physiotherapy program on some of the knee osteoarthritis symptoms including pain intensity, disability, knee joint range of motion, stride length and walking speed in patients with osteoarthritis

Design

Randomized clinical trial with control group, community based and practical, with parallel groups, no blinded, on 30 patients, randomization was performed by even-odd digits.

Settings and conduct

The study was performed at central Farhangian clinic in Tehran. Sampling was non-probability (convenient sampling) and patients were randomly allocated in two intervention and control groups (each groups included 15 patients). After interventions; pain, disability, range of motion, stride length and walking speed were measured at the beginning and at the end of the interventions and following 20 days after the last session too. Blinding was not performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria : The patients with knee osteoarthritis with intensity of 2 or 3 degree in Kellgren and Lawrence scale ; the age of patients is 40 - 65 years old; The most pain intensity that patient suffered in the last week is at least 30 of 100 on Visual Analog Scale. Non inclusion criteria: Bone Mass Intensity is more than 30 kg/m² ; suffering from systemic arthritis.

Intervention groups

Both groups will be treated by routine physiotherapy program for 10 sessions including: continuous ultrasound for 6 minutes on anterior and posterior of knee, then conventional TENS with hot pack around knee for 20 minutes and several type of exercises, but intervention group walk also with reverse heel shoes for 15 minutes

two times in a session ,before and after physiotherapy.

Main outcome variables

pain intensity , disability , knee joint range of motion , stride length and walking speed

General information

Reason for update

Trial completion

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071535097N1**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **prospective**

Last update: **2020-07-23, 1399/05/02**

Update count: **1**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Mohsen Shams

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7739 2705

Email address

mo.shams@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

personal funding source

Expected recruitment start date

2017-12-01, 1396/09/10
Expected recruitment end date
2018-03-01, 1396/12/10
Actual recruitment start date
2017-12-01, 1396/09/10
Actual recruitment end date
2018-04-09, 1397/01/20
Trial completion date
2018-09-11, 1397/06/20

Scientific title
The effect of walking with reverse heel shoes concomitant with routine physiotherapy program on pain, range of motion, stride length, walking speed and disability in patients with knee osteoarthritis

Public title
The effect of walking with reverse heel shoes on improving knee osteoarthritis symptoms

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age of patient between 40-65 years old Knee DJD intensity is 2-3 degree on Kellgren & Lawrence Symptoms beginning is gradual Not being occur after trauma or accident or fracture The most pain intensity that patient suffered in the last week would be at least 30 of 100 on Visual Analog Scale

Exclusion criteria:

Joint injection therapy in recent 3 months Knee joint ligament injury Body Mass Index is more than 30 kg/m² Systemic arthritis Using cane or crutch or walker

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

First patient and as the same manner the rest of patients who had odd numbers were placed in control group and second patient and the rest of patients with even numbers in intervention group

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation Sciences

Street address

Koodakyar Blind Alley , Daneshjoo Boulevard , Evin

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2017-10-18, 1396/07/26

Ethics committee reference number

IR.USWR.REC.1396.184

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description

Pain Intensity

Timepoint

Before intervention - After end of the intervention - 20 days following end of the intervention

Method of measurement

Visual Analog Scale

2

Description

Range Of Motion

Timepoint

Before intervention - After end of intervention - 20 days following end of the intervention

Method of measurement

Goniometer

3

Description

Walking speed

Timepoint

Befor intervention - After end of intervention - 20 days following end of the intervention

Method of measurement

10 meter walk test

4

Description

Stride length

Timepoint

Befor intervention - After end of intervention - 20 days following end of the intervention

Method of measurement

To meter walked 15 stride then division it per 15

5

Description

Disability

Timepoint

Befor intervention - After end of intervention - 20 days following end of the intervention

Method of measurement

Knee injury and Osteoarthritis Outcome Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Walking with reverse heel shoes in 15 minutes for two times in each session during 10 session plus routine physiotherapy including continuous ultrasound (1 MHZ frequency and 1 w/cm²) for 6 minutes then conventional TENS (100 HZ frequency and 50 microsecond so that can be sense with hot pack in anterior and posterior of knee for 20 minutes , resistance exercises for quadriceps , hip abductors and calf leg muscles

Category

Rehabilitation

2

Description

Control group: Routine physiotherapy including continuous ultrasound (1 MHZ frequency and 1 w/cm²) for 6 minutes then conventional TENS (100 HZ frequency and 50 microsecond so that can be sense with hot pack in anterior and posterior of knee for 20 minutes , resistance exercises for quadriceps , hip abductors and calf leg muscles

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Central Farhangian Clinic

Full name of responsible person

Mohsen Shams

Street address

Next to Fayazbakhsh Bus Terminal , Imam Khomeini Square

City

Tehran

Province

Tehran

Postal code

1114655111

Email

dfm@tehranedu.org

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Mohammad Reza Khodaei Ardakani

Street address

Koodakyar Blind Alley, Daneshjoo Boulevard, Evin

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Phone

+98 21 2218 0039

Email

Kh.ardakani@uswr.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of Social Welfare and Rehabilitation 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

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Mohsen Shams

Position

PhD candidate of Physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Koodakyar Blind Alley, Daneshjoo Boulevard, Evin

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 7739 4525

Fax**Email**

mo.shams@uswr.ac.ir

Web page address**Email**

mo.shams@uswr.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Mohsen Shams

Position

PhD candidate of Physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Koodakyar Blind Alley , Daneshjoo Boulevard , Evin

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 7739 4525

Fax**Email**

mo.shams@uswr.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Mohsen Shams

Position

PhD candidate of Physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Koodakyar Blind Alley, Daneshjoo Boulevard, Evin

City

Tehran

Province

Tehran

Postal code

1985713834

Phone

+98 21 7739 4525

Fax

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