

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### the effect of treatment based on movement system impairment classification theory in people with knee pain (a randomized control trial)

#### Protocol summary

##### Study aim

the investigation of the treatment effect based on movement system impairment classification theory in people with knee pain

##### Design

a randomized controlled trial with equivalent intervention and control groups, single blinded on 60 patients, consecutive simple individual randomization (in order of referral)

##### Settings and conduct

place: Shahid Beheshti physiotherapy clinic. After examination and diagnosis of movement impairment, the expert colleague classify them into intervention and control groups randomly. During 10 sessions in 6 weeks, researcher accomplishes the predetermined physiotherapy treatments for each group. data collection, outcome measure assessment , data analysis is done by the colleague, using questionnaires for investigating function and disability, visual analogue scale and video camera to recording knee projection angle

##### Participants/Inclusion and exclusion criteria

inclusion criteria: patients with knee rotational syndrome or patellar lateral glide syndrome. Pain at least 3 on the visual analog scale. knee Pain during running or jumping. exclusion criteria: pregnancy

##### Intervention groups

intervention1:patients with knee rotation syndrome with valgus control 1: patients with knee rotation syndrome with valgus intervention 2:patients with knee rotation syndrome with varus control 2: patients with knee rotational syndrome with varus intervention 3:patients with patellar lateral glide syndrome control 3: patients with patellar lateral glide syndrome similar treatments for control groups:10 sessions in 6 weeks: , electrotherapy,Ultrasound, exercices. intervention groups : the above treatment plus education and modification of functional activities, improve performance of hip lateral rotators and abductors and

extensibility of iliotibial band

##### Main outcome variables

pain intensity, disability Level, Function level, Knee frontal plane projection angle.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190222042801N1**

Registration date: **2020-12-17, 1399/09/27**

Registration timing: **retrospective**

Last update: **2020-12-17, 1399/09/27**

Update count: **0**

##### Registration date

2020-12-17, 1399/09/27

##### Registrant information

##### Name

Parisa Zamani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2019-08-23, 1398/06/01

##### Actual recruitment start date

2019-08-22, 1398/05/31

**Actual recruitment end date**

2019-08-22, 1398/05/31

**Trial completion date**

2019-08-22, 1398/05/31

**Scientific title**

the effect of treatment based on movement system impairment classification theory in people with knee pain (a randomized control trial)

**Public title**

the effect of physiotherapy on knee pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

patients with knee rotation syndrome or patellar lateral glide syndrome knee pain during running or jumping knee pain at least 3 on visual analog scale

**Exclusion criteria:**

Pregnancy

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

the sampling method in the present study is consecutive. It means that the expert colleague gets present at the patients' referral site (Shahid Beheshti rehabilitation clinic) from the beginning of the study, and patients who are eligible to participate in the study are identified and then, invited to participate in the study. Therefore, randomization is occurred consecutively. It should be noted that only one rehabilitation center is sampled in this study. In this study, simple randomization method is used and randomization unit is individual. In this way, the eligible participant with diagnosis of having one of the three identified movement impairment syndrome is classified to a primary group with the other ones with the same impairment first. then in each group with the same movement impairment people are numbered by order of their referral. individuals who the odd number assigned to them are included in intervention group and participants with the even numbers are included in control groups. for example, if the primary diagnosis is rotational syndrome with varus, number one is assigned to the first participant with this movement impairment and number two assigned to the second one with the same diagnosis. so the first odd number is included in intervention group for rotational syndrome with varus and the second person with this syndrome with even

number two is included to control group of the same subcategory and the way is continued until the assigned number of each group are entered in to the study for this diagnosis group. randomization for other subcategories are done the same way based on their primary diagnosis and by order of their referral.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In the present study, the expert experienced colleague who has passed more than 100 hours instructions in clinical diagnosis of movement system impairment is responsible to do: 1-Systematic examinations and diagnosis the movement system impairments of the clients 2- Randomization of participants into intervention or control groups. All of these procedures are done based on the study inclusion criterion and clinical recognition conceptions of the movement system impairment theory, furthermore; the researcher is blind to them. But all treatment sessions are done completely by the researcher. All intervention groups are treated specifically based on the movement system impairment classification theory for knee pain and all control groups treatments are based on routine treatment protocols for knee pain suggested by physiotherapy reference texts. Data collection in predetermined times is done by another co worker who is blind same as the researcher. Outcome measure assessment and data analysis are done by statistics consultant of the project but the researcher is also blind to all of these.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Ahwaz University of Medical Sciences

**Street address**

Jondishapour University of Medical Sciences., Golestan St., Golestan Hwy

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**Province**

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**Postal code**

61357-15794

**Approval date**

2019-01-15, 1397/10/25

**Ethics committee reference number**

IR.AJUMS.REC.1397.744

## Health conditions studied

### 1

#### Description of health condition studied

knee pain

#### ICD-10 code

M25.56

#### ICD-10 code description

knee Pain

## Primary outcomes

### 1

#### Description

pain intensity

#### Timepoint

Before treatment beginning, at the end of the third week in the middle of treatment period, at the end of the sixth week after treatment finishing and at the twelfth week the end of follow up period.

#### Method of measurement

with visual analog scale

### 2

#### Description

disability level

#### Timepoint

Before treatment beginning, at the end of the third week in the middle of treatment period, at the end of the sixth week after treatment finishing and at the twelfth week the end of follow up period.

#### Method of measurement

with knee injury and osteoarthritis outcome score questionnaire

### 3

#### Description

function level

#### Timepoint

Before treatment beginning, at the end of the third week in the middle of treatment period, at the end of the sixth week after treatment finishing and at the twelfth week, the end of follow up period.

#### Method of measurement

with lower extremity functional scale questionnaire

### 4

#### Description

knee joint frontal plane projection angle

#### Timepoint

Before treatment beginning, at the end of the sixth week after treatment finishing and the end of the twelfth week, after follow up period.

#### Method of measurement

with video camera and Kinovea software

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Patients with knee rotation syndrome with valgus who are given specific treatment based on movement system impairment classification theory within 10 sessions in 6 weeks. Each session takes one hour and a half including specific treatments plus routine ones. Specific treatments including: 1- Improve muscle performance of hip lateral rotators and abductors 2- Improve extensibility of iliotibial ( I.T.B) band 3- Posterior x taping of knee 4- Education and modification of functional activities that contribute to impaired motion of knee 5- address pronation foot; Routine physiotherapy treatments including: 1- Hot pack 2- Electrical stimulation ( inferential current around knee and functional electrical stimulation on knee muscles) 3- Ultrasound wave with 3 MHz frequency with continuous mode on lateral and posterior aspect of knee In the earlier four weeks, every week we should accomplish two treatment sessions and during two weeks after, each week one treatment session is done .

#### Category

Rehabilitation

### 2

#### Description

Intervention group 2: Patients with knee rotation syndrome with varus who are given specific treatment based on movement system impairment classification theory within 10 sessions in 6 weeks. Each session takes one hour and a half including specific treatments plus routine ones. Specific treatments including: 1- Improve muscle performance of hip lateral rotators and abductor 2- Improve extensibility of iliotibial ( I.T.B) band 3- Posterior x taping of knee 4- Education and modification of functional activities that contribute to impaired motion of knee 5- Improve shock absorb- heel to toe pattern; Routine physiotherapy treatments including: 1- Hot pack 2- Electrical stimulation ( inferential current around knee and functional electrical stimulation on knee muscles) 3- Ultrasound wave with 3 MHz frequency with continuous mode on lateral and posterior aspect of knee In the earlier four weeks, every week we should accomplish two treatment sessions and during two weeks after, each week one treatment session is done .

#### Category

Rehabilitation

### 3

#### Description

Intervention group 3: patients with patellar lateral glide syndrome who are given specific treatment based on movement system impairment classification theory within 10 sessions in 6 weeks. Each session takes one

hour and a half including specific treatments plus routine ones. Specific treatments including: 1-Limit prolonged knee flexion 2-Improve muscle performance of quadriceps 3- Improve extensibility of iliotibial band 4- Mobilization- patellar medial glide 5- Medial taping of patella; Routine physiotherapy treatments including: 1- Hot pack 2- Electrical stimulation ( inferential current around knee and functional electrical stimulation on knee muscles) 3- Ultrasound wave with 3 MHz frequency with continuous mode on lateral and posterior aspect of knee In the earlier four weeks, every week we should accomplish two treatment sessions and during two weeks after, each week one treatment session is done .

#### **Category**

Rehabilitation

#### **4**

##### **Description**

Control group 1: patients with knee rotation syndrome with valgus who are given the same routine physiotherapy treatment regardless of their movement impairment. Each session takes one hour and a half including: 1-Hot pack 2-Electrical stimulation ( inferential current around knee and functional electrical stimulation on knee muscles) 3- Ultrasound wave with 3 MHz frequency with continuous mode on lateral and posterior aspect of knee 4- Quadriceps strengthening exercise and stretching posterior muscles of the knee In the earlier four weeks, every week we should accomplish two treatment sessions and during two weeks after, each week one treatment session is done .

#### **Category**

Rehabilitation

#### **5**

##### **Description**

Control group 2: patients with knee rotation syndrome with varus who are given the same routine physiotherapy treatment regardless of their movement impairment. Each session takes one hour and a half including: 1-Hot pack 2-Electrical stimulation ( inferential current around knee and functional electrical stimulation on knee muscles) 3- Ultrasound wave with 3 MHz frequency with continuous mode on lateral and posterior aspect of knee 4- Quadriceps strengthening exercise and stretching posterior muscles of the knee In the earlier four weeks, every week we should accomplish two treatment sessions and during two weeks after, each week one treatment session is done .

#### **Category**

Rehabilitation

#### **6**

##### **Description**

Control group 3: patients with patellar lateral glide syndrome who who are given the same routine physiotherapy treatment regardless of their movement impairment. Each session takes one hour and a half including: 1-Hot pack 2-Electrical stimulation ( inferential current around knee and functional electrical stimulation

on knee muscles) 3- Ultrasound wave with 3 MHz frequency with continuous mode on lateral and posterior aspect of knee 4- Quadriceps strengthening exercise and stretching posterior muscles of the knee In the earlier four weeks, every week we should accomplish two treatment sessions and during two weeks after, each week one treatment session is done .

#### **Category**

Rehabilitation

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Physiotherapy clinic of Rehabilitation Faculty , Shahid Beheshti University of Medical Sciences

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

Dr. Mohammad Jafar Shaterzadeh Yazdi

###### **Street address**

Shahid Beheshti Physiotherapy Clinic., Physiotherapy group., Rehabilitation Faculty., Shahid Beheshti University of Medical Science., Damavand street ( in front of Buali Hospital)

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### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

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

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

Dr. Mehdi Ahmadimoghadam

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**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Jafar Shaterzadeh

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

Undecided - It is not yet known if there will be a plan to  
make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to

make this available  
**Clinical Study Report**  
Not applicable  
**Analytic Code**

Not applicable  
**Data Dictionary**  
Not applicable