

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Sep 2026

The effects of training program with virtual reality system on clinical indices and brain mapping of women with patellofemoral pain: A Randomized Clinical Trial study

Protocol summary

Study aim

The aim of this study is to determine the effects of training program with virtual reality system on clinical indices and brain mapping of women with patellofemoral pain (PFP).

Design

Randomized clinical trial with control group, with parallel groups, single-blind, 26 subjects

Settings and conduct

In this study, the effect of virtual reality training before and 8 weeks after intervention on clinical parameters and brain mapping is evaluated and the location of the study is the Faculty of Rehabilitation Sciences and School of Advanced Medical Sciences and Technologies; this is also blinded that the examiner and data analyzer will not be aware of which intervention will be administered to which subject. The patients aware of the existence of two different groups.

Participants/Inclusion and exclusion criteria

Women with PFP were included in this study and randomly divided into control and intervention groups. Inclusion criteria: women with PFP more than 6 months; right dominance; both knees involvement. Exclusion criteria: history of knee surgery; knee osteoarthritis; ligament pathology; physiotherapy or acupuncture in the past 3 months.

Intervention groups

There will be no intervention in the control group for 8 weeks and only training to daily activities (to prevent the development of PFP) will be given; Information such as how to sit properly, how often to use the stairs, proper footwear, prolonged exposure to a particular situation and etc. The intervention group will receive XBOX Kinect therapy in addition to the training provided to the control group. The intervention will be performed 3 times a week and each training session will last approximately 40 minutes. All training sessions will be conducted under

the supervision of a physiotherapist.

Main outcome variables

pain, balance, quality of life, function, brain mapping

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090831002391N40**

Registration date: **2019-10-23, 1398/08/01**

Registration timing: **prospective**

Last update: **2019-10-23, 1398/08/01**

Update count: **0**

Registration date

2019-10-23, 1398/08/01

Registrant information

Name

Zahra Rojhani Shirazi

Name of organization / entity

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of training program with virtual reality system on clinical indices and brain mapping of women with patellofemoral pain: A Randomized Clinical Trial study

Public title

The effects of training program with virtual reality on women with patellofemoral pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women between the ages of 18-40 years Anterior knee pain (in the back or around the patella) for at least 6 months Pain in the retropatellar area and around the knee in at least 2 of the following activities: prolonged sitting with bent knees, climbing stairs, squatting, running, kneeling, hopping / jumping Having symptoms in 2 of clinical tests: pain during patellar apprehension test, pain and crepitation during patellar compression test(in fact positive patellofemoral grinding test) Onset of pain without a history of trauma Pain in touch of the facet of patella 3 or more pain based on Visual Analogues Scale(VAS) while step up and down from a 25cm step or on squatting No pain above 7 on the VAS scale Lack of visual and neurological problems Right dominance Bilateral knee involvement Kujala questionnaire score less than 83 No use of drugs that affect balance in the past 72 hours

Exclusion criteria:

Knee osteoarthritis History of knee surgery History of patellar dislocation Laxity of ligament Patellar tendon or cartilage pathology Referred pain from lumbar spine Other abnormalities such as leg length discrepancy(more than 2 centimeter) Physiotherapy or acupuncture in the past three months History of epilepsy or cardiovascular disease Pregnancy Diabetes Rheumatic diseases Professional athlete

AgeFrom **18 years** old to **40 years** old**Gender**

Female

Phase

2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **26****Randomization (investigator's opinion)**

Randomized

Randomization description

Assignment of patients in two groups of intervention and

control was done by Block Balanced Randomization (BBR) method. The Randomization Sequence is generated with using the free web site at <http://www.randomization.com>. Non-transparent and sealed envelopes will be used to conceal the assignment of individuals to groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor will not be aware of which intervention will be administered to which subject. The data analyzer also does not know the groups (control or intervention).

Placebo

Not used

Assignment

Parallel

Other design features

All participants are invited to study through advertisements. According to related past studies the sample size estimated 22 subjects (11 subjects per groups) and with considering the 20% attrition with ratio of 1:1 (intervention group:control group) for each of group at least 13 subjects were considered. Assignment of people to groups will be based on the Block Balanced Randomization (BBR) method. After one month from the end of the study, follow up will be performed in both study groups just on clinical indicators.

Secondary Ids

empty

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

Ethics committee of research in Shiraz University of Medical Science

Street address

Central building of Shiraz University of Medical Science, Zand Ave

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-09-18, 1398/06/27

Ethics committee reference number

IR.SUMS.REHAB.REC.1398.027

Health conditions studied**1****Description of health condition studied**

Patellofemoral pain

ICD-10 code

M22.40

ICD-10 code description

Chondromalacia patellae, unspecified knee

Primary outcomes

1

Description

Balance

Timepoint

Before intervention and immediately after completion 8 weeks intervention قبل

Method of measurement

Modified Star Excursion Balance Test(SEBT)

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention and immediately after completion 8 weeks intervention

Method of measurement

SF-36 (Short Form Health Survey)questionnaire

2

Description

Function

Timepoint

Before intervention and immediately after completion 8 weeks intervention

Method of measurement

Step down test and Kujala Patellofemoral Scale

3

Description

Brain mapping

Timepoint

Before intervention and immediately after completion 8 weeks intervention

Method of measurement

Quantitative Electroencephalography(QEEG)

4

Description

Pain

Timepoint

Before intervention and immediately after completion 8 weeks intervention

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: The intervention group will receive training with XBOX Kinect 360 for 8 weeks in addition to the training provided to the control group. The intervention group will be trained 3 times a week. The games used in this study are from the three packages of Kinect adventures, Kinect Sport and Your Shape Fitness Evolved 2012. The intensity of the games will vary from easy to hard depending on each patient's ability and progress. Each training session lasts about 40 minutes, with each person warm up to 5 minutes before starting the game, and 5 minutes cool down after the game, and practicing XBOX for 30 minutes. All training sessions will be conducted under the supervision of a physiotherapist.

Category

Treatment - Other

2

Description

Control group: During the 8 weeks, the control group will continue their daily routine and no intervention will be performed in this group, only training necessary to manage their daily activities (to prevent the development of patellofemoral pain) will be given. educations are provided to people with a prepared text that includes information on how to sit properly, manage of use the stair, proper footwear, no prolonged exposure to a particular situation, use of toilets, etc.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz school of rehabilitation

Full name of responsible person

Naghmeh Ebrahimi

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Abiverdi 1 street, Chamran blvd , School of Rehabilitation Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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, Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Naghmeh Ebrahimi

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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**Person responsible for scientific
inquiries**

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Name of organization / entity

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Associate professor

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Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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