Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

Phone

+98 71 1627 1552

Email address

rojhaniz@sums.ac.ir

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
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target 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 interventionقبل
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
Street address
Abiverdi 1 street, Chamran blvd , School of Rehabilitation Sciences
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3626 1081
Email
n_ebrahimi@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person

Younes Ghasemi

Street address
Central building of Shiraz University of Medical Science, Zand Ave

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3235 7282

Email
ghasemiy@sums.ac.ir

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

Street address
School of Rehabilitation, Abiverdi street, Chamran blvd

City
Shiraz

Province
Fars

Postal code
7194733669

Phone
+98 71 3626 1081

Email
n_ebrahimi@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Zahra Rojhani Shirazi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
School of Rehabilitation, Abiverdi 1 street, Chamran blvd

City
Shiraz

Province
Fars

Postal code
7194733669

Phone
+98 71 3626 1081

Email
rojhaniz@sums.ac.ir

Person responsible for updating data

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

Street address
School of Rehabilitation, Abiverdi 1 street, Chamran blvd

City
Shiraz

Province
Fars

Postal code
7194733669

Phone
+98 71 3626 1081

Email
n_ebrahimi@sums.ac.ir

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