Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effectiveness of a blended care Tele-rehabilitation Versus face-to-face Physical Therapy on Pain, Physical Function and Quality of Life in individuals with Patellofemoral Pain Syndrome: A Single Blind Randomized Controlled Trial

Protocol summary

Study aim
the Effectiveness of Tele-rehabilitation Versus face-to-face Physical Therapy on Pain, Physical Function and Quality of Life

Design
A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 60 patients. Random Allocation computer software (version 1.1, Isfahan University of Medical Sciences, Iran) is used for randomization.

Settings and conduct
Physical therapy clinics of the rehabilitation school of AJUMS.The treatment in the intervention group is performed in the form of Tele-rehabilitation and 3 face-to-face counseling sessions for 6 weeks and 3 sessions per week (18 sessions in total). Tele-rehabilitation is done through the vito app software. The treating physiotherapist is the same in both face-to-face treatment and Tele-rehabilitation groups. The evaluating physiotherapist is blinded to the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 and 45 years, Access to the internet and mobile phone, Anterior knee pain following going up and down stairs, knee flexion and sitting for a long time, knee pain for at least 1 month Exclusion criteria: knee ligament instability, Knee meniscus pathologies, Patellar tendinopathy or Iliotibial Band tendinopathy, Knee joint effusion, Knee Subluxation or Dislocation or Fracture, Sinding-Larsen-Johansson syndrome, Plica syndrome, Osgood-Schlatter disease, Neuromuscular, rheumatologic or metabolic diseases, Having undergone conservative or surgical treatment of the affected knee less than 6 months previously

Intervention groups
The intervention group will receive 18 sessions of muscle stretching exercises, muscle strengthening, balance and functional exercises through a remote rehabilitation software. The control group also receives the exercises in the clinic in person.

Main outcome variables
pain level, Physical function, Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201112049361N1**
Registration date: **2022-10-29, 1401/08/07**
Registration timing: **prospective**

Last update: **2022-10-29, 1401/08/07**
Update count: **0**

Registration date
2022-10-29, 1401/08/07

Registrant information

Name
Masumeh Hessam

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3336 3036

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hesam-m@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-01, 1401/08/10

Expected recruitment end date

2023-06-20, 1402/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of a blended care Tele-rehabilitation Versus face-to-face Physical Therapy on Pain, Physical Function and Quality of Life in individuals with Patellofemoral Pain Syndrome: A Single Blind Randomized Controlled Trial

Public title

The Effect of Telerehabilitation on Knee Pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having knee pain for at least 1 month Access to internet and mobile phone not attended in physical therapy program or sport activity Anterior or posterior knee pain following going up and down stairs, knee flexion and sitting for a long time

Exclusion criteria:

knee ligament instability Knee meniscus pathologies Patellar tendinopathy or Iliotibial Band tendinopathy Knee joint effusion Knee Subluxation or Dislocation or Fracture Sinding-Larsen-Johansson syndrome Plica syndrome Osgood-Schlatter disease Neuromuscular, rheumatologic or metabolic diseases Having undergone conservative or surgical treatment of the affected knee less than 6 months previously

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After completing the outcome measurement tests before treatment intervention, people are divided into two groups of tele- rehabilitation treatment and face-to-face physical treatment group using the Permuted Block Stratified randomization method. In this method, the allocation of people into two groups is done with the same sample size - and also the balance of the groups is maintained in terms of the dispersion of the influential variables (age, gender, and activity level in this study). RandomAllocation computer software (version 1.1, Isfahan University of Medical Sciences, Iran) is used for randomization. First, a random order of two letters A (remote rehabilitation combined treatment group) and B (face-to-face physical therapy group) is made in blocks with random numbers of 4 and 6 (for example, ABBA and ABAABB). Then the blocks are hidden by the opaque envelope. The randomization process will be done by a person who is not involved in any of the other stages of the research.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the fact that the type of study is such that the participants and the physiotherapist are aware of the type of intervention that participants receive, it is not possible to blind the patients and the physiotherapist. All evaluations are done by a physiotherapist who is not aware of the type of intervention that the participants receive. The people participating in the study are told not to disclose the type of intervention to the physiotherapist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jundishapur University of Medical Sciences

Street address

Faculty of Rehabilitation Sciences, Jundishapur University of Medical Sciences, Golestan highway, Ahvaz, Iran.

City

Ahvaz

Province

Khouzestan

Postal code

33133-61357

Approval date

2022-10-01, 1401/07/09

Ethics committee reference number

IR.AJUMS.REC.1401.282

Health conditions studied

1

Description of health condition studied

Patellofemoral Pain Syndrome

ICD-10 code

M22.40

ICD-10 code description

Chondromalacia patellae, unspecified knee, Patellofemoral disorders, Disorders of patella

Primary outcomes

1

Description
pain level
Timepoint
Before the start of treatment/ at the end of the sixth week of treatment intervention/ 1 month after the end of the treatment period
Method of measurement
Visual analogue scale

2

Description
Physical function
Timepoint
Before the start of treatment/ at the end of the sixth week of treatment intervention/ 1 month after the end of the treatment period
Method of measurement
Physical function section of kujala questionnaire, Step down test, Bilateral squat test and Antero-medial lunge test

3

Description
Quality of life
Timepoint
Before the start of treatment/ at the end of the sixth week of treatment intervention/ 1 month after the end of the treatment period
Method of measurement
Quality of life section of knee injury and osteoarthritis outcome score questionnaire

Secondary outcomes

1

Description
adherence to the treatment plan
Timepoint
Before the start of the treatment/ at the end of the sixth week of treatment intervention/ 1 month after the end of the treatment period
Method of measurement
based on the number of treatment sessions that patients have participated in face-to-face physical therapy group; based on the application calendar in tele-rehabilitation group.

Intervention groups

1

Description
Intervention group: exercise therapy which includes stretching exercises, strengthening exercises, balance exercises and functional exercises for 6 weeks, 3 sessions every week and 18 sessions totally with application and based on tele-rehabilitation
Category
Rehabilitation

2

Description
Control group: face to face exercise therapy which includes stretching exercises, strengthening exercises, balance exercises and functional exercises for 6 weeks, 3 sessions every week and 18 sessions totally at physical therapy clinic.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Jundishapur University of Medical Sciences, Rehabilitation Faculty
Full name of responsible person
Dr. Masumeh Hessam
Street address
Faculty of Rehabilitation, Ahvaz Jundishapur University of Medical Sciences, Golestan boulevard, Ahvaz, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr.Mehrnosh Zakerkish
Street address
Vice President of Research and Technology of Ahvaz Jundishapur University of Medical Sciences and Health Services, Ahvaz, Ahvaz Jundishapur University of Medical Sciences.
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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. Masumeh Hessam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Department of Physiotherapy. Ahvaz, Faculty of Rehabilitation Sciences, Jundishapur University of Medical Sciences, Ahvaz, Iran

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

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

Title and more details about the data/document

The data from primary outcomes will be available.

When the data will become available and for how long

3 months after the published paper

To whom data/document is available

Data will be available for researchers that work at Universities and scientific centers.

Under which criteria data/document could be used

Responsiveness analysis can be done.

From where data/document is obtainable

Contact with project executive manager email address: hessam_pt81@yahoo.com Contact with project assistance email address: negramir@yahoo.com referring to rehabilitation faculty of Ahvaz Jundishapur University of Medical Sciences

What processes are involved for a request to access data/document

Researchers who want to use study data should give a written application to executive manager of the project and after consultation with other study team members , data will be available.

Comments