Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Home-based Rehabilitation Ttraining on Pain, Performance, General Health and Quality of Life in Patients with Knee Osteoarthritis

Protocol summary

Summary

Objective: The effect of home-based rehabilitation training on pain, performance, general health and quality of life in patients with knee osteoarthritis Methodology: This is an experimental study. Samples of this study were 74 patients who conformed to the inclusion criteria (no history of surgical-related disease, having radiological symptoms of osteoarthritis in knee with a physician's approval, and non-use of an intra-articular injectable drug). They were selected among all patients with knee osteoarthritis referring to the clinic Nos. 2 of Persian Gulf Bushehr from 2017/10/23 to 2018/02/20. They were assigned to two intervention and control groups by randomized blocking method. Research intervention for each intervention group was three 1-hour training sessions that took place individually and face-to-face over the course of 3 consecutive days and follow up was continued for two months after home-based training but it was not given to the educational control group. Pain, performance, general health and quality of life in both groups before and after two months of intervention were measured using a visual analog scale of pain, a questionnaire, a general health questionnaire, and a (SF-12) questionnaire. Data analysis was done by descriptive statistical tests and at a significant level of 95%. Outcome: Rehabilitation training by nurses, as an inexpensive, accessible and effective intervention at home, is expected to be an effective step in reducing pain, improving performance, general health and quality of life in patients with knee osteoarthritis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100218117N2**
Registration date: **2017-11-19, 1396/08/28**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Home-based Rehabilitation Ttraining on Pain, Performance, General Health and Quality of Life in Patients with Knee Osteoarthritis

Public title

The Effect of Home-based Rehabilitation on the Treatment of Knee Qsteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: No history of surgical related disease (such as joint replacement, joint repair), having radiological symptoms of osteoarthritis in knee with a physician's approval, non-use of an intra-articular injectable drug, the absence of any mental and psychological illness according to the patient's own statements, and independence in self-care. Exclusion criteria: The first referral of the patient and the lack of diagnosis by the doctor, the lack of regular referral of the patient, the patient's reluctance to continue treatment, and exacerbation of symptoms.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethics Committee of Bushehr University of Medical Sciences

Street address

University of Medical Sciences, Rishehr St,Bushehr, Iran

City

Bushehr

Postal code

7518759577

Approval date

2017-09-27, 1396/07/05

Ethics committee reference number

IR.BPUMS.Rec.1396.82

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

Timepoint

Before the intervention, two months after the intervention

Method of measurement

Visual Scale of Pain

2

Description

Performance

Timepoint

Before the intervention, two months after the intervention

Method of measurement

Scale KOOS

3

Description

general health

Timepoint

Before the intervention, two months after the intervention

Method of measurement

General Health Questionnaire

4

Description

Quality of Life

Timepoint

Before the intervention, two months after the intervention

Method of measurement

Quality of Life Questionnaire (SF-36)

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group: Implementation of three 1-hour sessions "Individual training and practice in the following order: The first training session on knee osteoarthritis,

the causes of symptoms, symptoms, and a simple language diet for one hour is explained. The second session is about the pharmaceutical diet, proper sitting and lifting, and the patient is asked to practice in the presence of the researcher in order to ensure that it is accurate. The third session is about exercising and Range of Motion (ROM) exercises, and the patient is required to perform exercises in the presence of a researcher in order to ensure that it is accurate. Also, a review of the two sessions is done and the questions are answered to the patient and will be provided to the patients at the end of the session on the educational curriculum related to the training sessions. The patient is then asked to repeat the stretching exercises on a daily basis and how to sit up and get up and keep up-to-date, and complete all the training tips and exercises for two months, and a checklist of hints and exercises that should be done throughout the day. He will be given a mark on them. The checklist is also available to the researcher, and the researcher will contact the patient once a week to ensure that he or she is practicing and observing educational issues".

Category

Rehabilitation

2

Description

"The control group: does not receive rehabilitation training and receive routine therapies."

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic No. 2 of the Persian Gulf Shohada

Full name of responsible person

Zahra Hoseinabadi

Street address

Clinic No. 2 of the Persian Gulf Shohada, Justice Crossroads, Bushehr, Iran.

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Bushehr University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Khamisipour

Street address

University of Medical Sciences, Rishahr St, Bushehr, Iran.

City

Bushehr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Bushehr University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Zahra Hosseinabadi

Position

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty