

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the short-term effects of clinically supervised and Internet-based exercise therapy on pain, range of motion, and function in patients with knee osteoarthritis: a randomized clinical trial.

Protocol summary

Study aim

Comparison of Short-Term Effects of Clinically Supervised and Internet-Based Exercise Therapy on Pain, Movement Range, and Performance in Patients with Knee Osteoarthritis.

Design

First, an overview of the study is presented for the participants, then the research checklist, which contains questions about demographic information and the medical history, as well as questions about the intensity of knee pain, is completed by the researcher. Then, other clinical and functional assessments will be carried out.

Settings and conduct

Hazrat Rasool Akram Hospital-Sports Medicine Clinic

Participants/Inclusion and exclusion criteria

Participants included of women aged 50 to 75 years old with primary osteoarthritis of the knee were randomly assigned to one of two groups: Internet-based Exercise Therapy (intervention group) or Supervised Exercise Therapy (control group).

Intervention groups

Internet-based Exercise Therapy(IET) (Intervention group) and Supervised Exercise Therapy (SET) (Control group).

Main outcome variables

Pain, Knee range of motion, Thigh girth, Physical function.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101228005486N8**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **prospective**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

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Azar Moezy

Name of organization / entity

Iran university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-15, 1400/02/25

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the short-term effects of clinically supervised and Internet-based exercise therapy on pain, range of motion, and function in patients with knee osteoarthritis: a randomized clinical trial.

Public title

Therapeutic exercise in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primary OA of the knee joint grade 2, 3 according Kellgren and Lawrence scale; Female gender; Age between 50-75; Knee pain for at least six months and with intensity 4 on the VAS scale in activities such as going up and down stairs, sitting and squat; Normal mental state; Ability to walk independently for at least 30 meters BMI equal or less than 30; Patient's consent to participate in the research; Familiarity how to use the Internet and social media for the Internet-based Exercise Therapy (IET) group.

Exclusion criteria:

History of knee intra-articular injection in the past six months; History of neuromuscular disease; History of knee traumatic injuries approved by the physician; History of lower limb surgery during the last year; Bone implants, History of new fractures in lower limbs; Malignant tumors; Participating in exercise therapy and physical therapy programs in the recent three months; History of chronic disease or any conditions that known to affect the study;

Age

From **50 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the Restricted Randomization method of Block Randomization will be used to ensure that the number of samples allocated to each of the study groups is equal. Random Allocation Software (Latest Version) will also be used as a randomization tool; it is free to use for academic study and can be found at: <http://www.msaghaei.com/Softwares/dnld/RA.zip>. This software, in addition to simple randomization, will produce random sequences using the blocking method.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the assessor will be blinded to the study groups. The outcomes will be evaluated pre and post intervention by a sports medicine assistant who will be blind to the presence of patients in the groups. Furthermore, the data obtained from the study will be analyzed by a statistician who is not aware of the patient groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University Of Medical Sciences, Hemat Highway next to Milad Tower

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-02-08, 1399/11/20

Ethics committee reference number

IR.IUMS.FMD.REC.1399.628

Health conditions studied

1

Description of health condition studied

Primary knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Pain

Timepoint

Pre- and post-intervention

Method of measurement

VAS pain scale

2

Description

Active knee range of flexion

Timepoint

Pre- and post-intervention

Method of measurement

Goniometry

3

Description

Thigh girth

Timepoint

Pre- and post-intervention

Method of measurement

With centimeter tape

Secondary outcomes

1

Description

Functional Tests

Timepoint

Pre- and post-intervention

Method of measurement

Timed Up & Go Test and Six-Minute Walk Test

Intervention groups

1

Description

Intervention group: Internet-based Exercise Therapy(IET) group-First, Internet connectivity and instant message systems will be examined for patients in the Internet-based exercise therapy group. In this study, an exercise therapy manual is prepared for the IET group, along with pictures of how to perform the exercise, and it will be given to them the day before the intervention, and they will be asked to follow their exercise therapy protocol similar to the control group and to exercise three times a week for six weeks (a total of 18 sessions). The researcher has used the messenger application to create an Internet group for IET group patients, where they would be able to get information about osteoarthritis of the knee, the procedure of exercise training, and general advice in the form of pictures and animations. This approach allows patients to share their feelings about the disease, symptoms, and exercise treatment, as well as communicate ideas about it. This, of course, would allow patients to continue with their exercise therapy. Furthermore, brief tutorial videos about doing exercise protocols will be prepared and submitted to each patient separately via the messaging application, and if the patient has any questions about doing exercises, she will use the video call choice to learn how to do exercises online or be monitored online and receive sufficient verbal and visual input to execute the correct exercises. Moreover, to ensure the exercise is performed, the researcher calls the patient and a close relative who stays with her on three pre-arranged days and asks questions about how the patient workouts and responds and record them in a logbook that will be prepared for each patient. The exercise protocol for patients with knee osteoarthritis in this study is the same for all participants in both the intervention and control groups, and it includes strengthening exercises to improve thigh muscle strength and stretching exercises to increase the flexibility of the soft tissues around the joint and increase

the range of motion. Some exercises have been designed based on the findings of numerous research to enhance the function and coordination of the patients.

Category

Rehabilitation

2

Description

Control group: Supervised Exercise Therapy (SET)- Patients in the exercise therapy group will be supervised by a physical medicine assistant at sports medicine clinic for six weeks, alternating three days per week, for a total of 18 sessions under an exercise therapy protocol similar to the IET group. It is worth noting that all exercises will be done in the same protocol for both lower limbs. In the SET group, as in the intervention group, the same questions are asked about how the patient completes exercises and reacts, and this detail is recorded in a logbook that is personalized for each patient. The exercise protocol for patients with knee osteoarthritis in this study is the same for all participants in both the intervention and control groups, and it includes strengthening exercises to improve thigh muscle strength and stretching exercises to increase the flexibility of the soft tissues around the joint and increase the range of motion. Some exercises have been designed based on the findings of numerous research to enhance the function and coordination of the patients.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Akram Hospital

Full name of responsible person

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1

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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 & Technology, Iran
University of Medical Sciences
Proportion provided by this source
20
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
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Dr Bita Zoghalchi
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A portion of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long

One year after the publication of articles related to the research project

To whom data/document is available

Researchers and specialists working in universities and health centers

Under which criteria data/document could be used

Analysis on the data delivered after obtaining permission from the researchers

From where data/document is obtainable

Dr Azar Moezy -Sports Medicine Department, Hazrat Rasool Akram Hospital, Niayesh St, Sattarkhan Ave, Zip code:14455613131,Tehran.

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

The applicant of the data file should send a request to the researcher via email and the researcher will notify the applicant after negotiating with other research colleagues, and this procedure will take a period of one month.

Comments