Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative study of the effect of using a mobile phone-based application to manage the exercise program of patients with chronic back pain referring to the physical medicine clinic of Imam Khomeini Hospital with the conventional method

Protocol summary

Study aim
Determining the effect of using a mobile phone-based application to manage the exercise program of patients with chronic back pain referring to the physical medicine clinic comparing the conventional method

Design
A controlled, randomized, parallel-group clinical trial on 98 patients. Randomization using the blocked randomization method

Settings and conduct
An application will be designed. Patients at the physical medicine clinic of Imam Khomeini Hospital of Tehran will log in daily and receive the exercises, and provide feedback after each exercise. Exercises are taught to patients using videos along with explanations, and the patient performs the exercises for 12 weeks. The control group are taught the usual method in the clinic and are provided with an pamphlet and an 84-cell chart to assess patient adherence.

Participants/Inclusion and exclusion criteria
Inclusion: Adults over 18 with chronic low back pain lasting more than 12 weeks, with or without radicular symptoms; whit persistent pain (at least 3 on a numerical rating scale); with regular (weekly) use of an internet-connected device; and fluency in Persian (spoken&written) Exclusion: Any spinal surgery within the past 12 months; evidence of spinal cord compression or cauda equina; severe spinal stenosis as evidenced by signs of neurogenic claudication (grade 3-4); fibromyalgia or systemic/inflammatory disorders; concurrent health conditions that prevent active participation in increased levels of physical activity, Cardiopulmonary disease; back pain resulting from an accident in the past 12 months or ongoing litigation; current or planned pregnancy

Intervention groups
Group using an app to manage their training program. Group whose training program is managed by traditional approach.

Main outcome variables
visual analog scale (VAS) score, Modified Oswestry Disability Index (MODI) score, adherence score, Satisfaction level

General information

Reason for update

Acronym
LBP

IRCT registration information
IRCT registration number: **IRCT20260202068736N1**
Registration date: **2026-07-26, 1405/05/04**
Registration timing: **prospective**

Last update: **2026-07-26, 1405/05/04**
Update count: **0**

Registration date
2026-07-26, 1405/05/04

Registrant information
Name
Mehrshad Mohammadpour
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6696 5500
Email address
mehrshadmp97@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01
Expected recruitment end date
2027-03-20, 1405/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the effect of using a mobile phone-based application to manage the exercise program of patients with chronic back pain referring to the physical medicine clinic of Imam Khomeini Hospital with the conventional method

Public title
Comparative study of the effect of using a mobile application to manage the exercise program of patients with chronic low back pain with the conventional method
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with chronic back pain
Exclusion criteria:
Any type of spinal surgery in the past 12 months Evidence of spinal cord compression or cauda equina syndrome Severe spinal stenosis as evidenced by signs of neurogenic claudication (grade 3 to 4) Fibromyalgia or systemic/inflammatory disorders Co-existing medical conditions that prevent active participation in increased levels of physical activity Cardiopulmonary diseases Back pain resulting from a traffic accident in the past 12 months or ongoing litigation Current or planned pregnancy
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **98**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly assigned to two groups (intervention group and control group). The randomization process will be performed by an independent person from the study who is not involved in any of the assessment or intervention phases, and will be performed using a random block design with variable block sizes (e.g., 4 or 6). The randomization sequence will be generated by computer software and the allocation results will be kept in opaque, sealed, numbered envelopes. These envelopes will only be opened at the time of patient allocation to the group and after baseline assessments have been completed to prevent allocation bias (allocation concealment).
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
Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences
Street address
Keshavarz Boulevard, corner of Qods, Tehran University of Medical Sciences Headquarters, 6th floor.
City
Tehran
Province
Tehran
Postal code
1417913191
Approval date
2025-07-29, 1404/05/07
Ethics committee reference number
IR.TUMS.IKHC.REC.1404.245

Health conditions studied

1

Description of health condition studied
chronic low back pain
ICD-10 code
M54.5
ICD-10 code description
Low back pain

Primary outcomes

1

Description
Percentage of adherence to the exercise program
Timepoint
Before the start of the intervention and 12 weeks after the intervention
Method of measurement
Checking the days the patient exercised through the app

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will register in the app with the mobile number they provided at the clinic and it will set a daily reminder for exercise time. They will then log in to the app daily and receive the exercises for that day and give feedback after each exercise. The patient's exercise program is personalized based on the feedback provided. The exercises are taught to the patients with GIFs along with Persian explanations, and then the patient performs the exercises in the amount prescribed by the app for 12 weeks.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini hospital

Full name of responsible person
Mehrshad Mohammadpour

Street address
End of Keshavarz Boulevard, Imam Khomeini Hospital

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Tehran

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Tehran

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+98 21 6658 1625

Email
Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ramin Kordi

Street address
Keshavarz Boulevard, corner of Qods Street, Central University Organization, 6th Floor, Vice President for Research and Technology

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Phone
+98 21 8163 3698

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vcr@tums.ac.ir

Web page address
https://ikhc.tums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mehrshad Mohammadpour

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Masoud Ghahveh Chi Akbari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Respecting the privacy of patients

Study Protocol

No - There is not 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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available