

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The comparison of delivering low back exercises by an smartphone application and traditional methods in non-specific chronic low back pain

Protocol summary

Study aim

The comparison of delivering low back exercises by an smartphone application and traditional methods in non-specific chronic low back pain

Design

Clinical trial with control group, with parallel groups, not blind, randomized, on 40 patients, envelope is used for randomization

Settings and conduct

study will be performed in the physiotherapy centers of Tabriz Rehabilitation faculty. Patients will receive ten sessions of physiotherapy with home exercises.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Low back pain patients aged 18-60 years who have had low back pain for more than 3 months, no specific cause for low back pain Has been identified and physiotherapy has been prescribed. Pain intensity is mild to moderate (VAS 2 to 6). The Oswestry questionnaire score should be higher than 10 before starting treatment. Have at least one smartphone in the patient's family. The person has the ability to read and understand the Persian language. Exclusion criteria: cases such as infection and spinal tumors, osteoporosis and vertebral fractures History of spinal surgery in the last 6 months Injury to the knee and ankle that restricts movement People whose symptoms are reproduced at the beginning of the slump test during neck flexion People with spinal deformities

Intervention groups

In this study, patients with chronic low back pain are divided into two groups: doing exercises with a mobile phone application and an exercise booklet. Both groups will receive the same exercises, except that in the smartphone app group, people will be able to use therapist support, send daily reports and watch exercise videos, and in the exercise booklet group, people can read photos and descriptions of exercises.

Main outcome variables

Pain intensity, disability, lumbar neuromuscular control,

neurodynamic, Adherence to exercise, compliance with treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210316050727N2**

Registration date: **2021-08-30, 1400/06/08**

Registration timing: **prospective**

Last update: **2021-08-30, 1400/06/08**

Update count: **0**

Registration date

2021-08-30, 1400/06/08

Registrant information

Name

Abas Soltani someh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3337 5359

Email address

ab.soltani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of delivering low back exercises by an smartphone application and traditional methods in non-specific chronic low back pain

Public title

The comparison of delivering low back exercises by an smartphone application and traditional methods in non-specific chronic low back pain

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Low back pain patients aged 18-60 years who have had low back pain for more than 3 months, no specific cause for low back pain has been identified and physiotherapy has been prescribed. Mild to moderate pain intensity (VAS 2 to 6) The Oswestry questionnaire score is above 10 before starting treatment. Have at least one smartphone in the patient's family. The person has the ability to read and understand the Persian language.

Exclusion criteria:

cases such as infection and spinal tumors, osteoporosis and vertebral fractures History of spinal surgery in the last 6 months injury to the knee and ankle that restricts movement People whose symptoms are reproduced at the beginning of the slump test during neck flexion People with spinal deformities and ankylosing spondylitis

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, Random software allocation For the allocation concealment, the type of intervention received is written on a piece of paper and placed inside the opaque envelopes and the back of the envelope will be numbered. The envelopes will be opened according to the entry of the participants and the type of group for each patient will be specified accordingly.

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 Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Department of Physiotherapy, School of Rehabilitation Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5355116553

Approval date

2021-05-03, 1400/02/13

Ethics committee reference number

IR.TBZMED.REC.1400.126

Health conditions studied

1

Description of health condition studied

Chronic non-specific low back pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain Intensity

Timepoint

At the beginning of the study (before the intervention) and after the end of treatment (one month later at the end of physiotherapy sessions), and two months after the start of treatment

Method of measurement

Visual analog scale

2

Description

Functional disability

Timepoint

At the beginning of the study (before the intervention) and after the end of treatment (one month later at the end of physiotherapy sessions), and two months after the start of treatment

Method of measurement

Oswestry questionnaire

Secondary outcomes

1

Description

Low back neuromuscular control

Timepoint

At the beginning of the study (before the intervention) and after the end of treatment (one month later at the end of physiotherapy sessions), and two months after the start of treatment

Method of measurement

Double leg lowering test

2

Description

Neurodynamic

Timepoint

At the beginning of the study (before the intervention) and after the end of treatment (one month later at the end of physiotherapy sessions), and two months after the start of treatment

Method of measurement

Straight leg raise test

3

Description

Patient satisfaction with treatment

Timepoint

after the end of treatment (one month later at the end of physiotherapy sessions), and two months after the start of treatment

Method of measurement

Special satisfaction questionnaire for this study

4

Description

Adherence to home exercise program

Timepoint

after the end of treatment (one month later at the end of physiotherapy sessions), and two months after the start of treatment

Method of measurement

Exercise Adherence Questionnaire

Intervention groups

1

Description

Intervention group: The duration of interventions is 4 weeks with one month of follow-up. Patients are visited three times a week in the physiotherapy centers of the School of Rehabilitation and the interventions will be performed under the supervision of the project researchers. The duration of each exercise therapy session can vary depending on the stage of the treatment protocol and the number of exercises. Due to the difficulty of stabilizing exercises and the emphasis on

doing the exercises correctly, patients in both groups are given a period of time to learn basic and basic exercises with the help of compression biofeedback, and then a 4-week treatment protocol with one month of follow-up. begins. In both groups, people first do some general stretching exercises to warm up before the main exercises; In the case of neurodynamic exercises, 4 exercises are considered that will be used only for patients with chronic low back pain who have pain referred to the lower extremities. Each neurodynamic exercise is performed one set of 20 per day. In the case of stabilization exercises, each exercise is held for 5 to 10 seconds and repeated 10 times a day (a set of ten). Each session adds one exercise to the patient's exercises so that in the first 4 weeks the patient receives all the relevant exercises and in the next 4 weeks repeats all the exercises; During this period, the number and timing of the exercises are improved. At the end of this section, the exercise schedule is set, but this schedule may change slightly depending on the patient's ability and skills. The patient is asked to do the exercises on a daily basis at home. Using the application in the treatment group is to examine the importance of using technology in the field of physiotherapy. In this regard, in order to prevent forgetfulness and doing wrong exercises in the application group, these exercises are provided to people through the application, which includes an instructional video of doing the exercises, teaching tips about back care, contacting the therapist, and sending a reminder message. Doing exercises and the message of doing or not doing exercises by the person is sent to the therapist through the application.

Category

Rehabilitation

2

Description

Control group: The duration of interventions is 4 weeks with one month of follow-up. Patients are visited three times a week in the physiotherapy centers of the School of Rehabilitation and the interventions will be performed under the supervision of the project researchers. The duration of each exercise therapy session can vary depending on the stage of the treatment protocol and the number of exercises. Due to the difficulty of stabilizing exercises and the emphasis on doing the exercises correctly, patients in both groups are given a period of time to learn basic and basic exercises with the help of compression biofeedback, and then a 4-week treatment protocol with one month of follow-up. begins. In both groups, people first do some general stretching exercises to warm up before the main exercises; In the case of neurodynamic exercises, 4 exercises are considered that will be used only for patients with chronic low back pain who have pain referred to the lower extremities. Each neurodynamic exercise is performed one set of 20 per day. In the case of stabilization exercises, each exercise is held for 5 to 10 seconds and repeated 10 times a day (a set of ten). Each session adds one exercise to the patient's exercises so that in the first 4 weeks the patient receives all the relevant exercises and in the next 4 weeks repeats all

the exercises; During this period, the number and timing of the exercises are improved. At the end of this section, the exercise schedule is set, but this schedule may change slightly depending on the patient's ability and skills. The patient is asked to do the exercises on a daily basis at home. In the control group, the exercises and tips for taking care of the back are provided through a tutorial booklet with explanations and it is recommended to him to set phone alarm in order to not forget doing home exercises.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic of Tabriz Rehabilitation faculty

Full name of responsible person

Abbas Soltani Somee

Street address

Tabriz,Tavanir,physiotherapy clinic of rehabilitation sciences

City

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5355116553

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Ab.soltani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

Street address

Tabriz University of Medical Sciences, Research Vice-Chancellor, Golgasht Street

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Samiei.moh@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Abbas Soltani Somee

Position

Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Tabriz

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abbas Soltani Somee
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Assistant
Latest degree
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Other areas of specialty/work
Physiotherapy
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Tabriz, Tavanir, physiotherapy clinic of rehabilitation sciences
City
Tabriz
Province

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

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable