

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of online and face-to-face cognitive exercises in people with non-specific chronic low back pain

Protocol summary

Study aim

Comparison of the effect of online and face-to-face cognitive exercises on pain, performance, disability, psychological factors and health status in people with chronic non-specific low back pain

Design

A clinical trial with a control group, with parallel groups, single blind, randomized, on 66 patients and Excel software rand function was used for randomization.

Settings and conduct

A total of 66 patients with non-specific chronic low back pain who are eligible for the study are randomly assigned to three groups. The treatment in all three groups will be 18 sessions for 12 weeks. 3 sessions for education and 15 sessions of exercises for each group will be performed by the researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women and men 25 to 55 years old
Minimum time for low back pain is 12 weeks and 3 days a week
People are in the medium risk group according to the Start Back tool Score 14% or more on Oswestry Disability Index
Pain intensity equal to or greater than 4 on a numerical rating scale
Have not taken any new medication or people who do not need medication during the 6 weeks before and during the study.
Exclusion criteria: Pregnancy
People with a history of lumbar tumors
Participate in exercise therapy courses for the treatment of low back pain in the past year
Cardiovascular problems
Having referral criteria for surgery such as severe sciatica
Having any fractures and surgery in the lumbar and dorsal spine
Existence of another painful disease (fibromyalgia, neuropathy, rheumatoid arthritis)

Intervention groups

1-online Pain education + motor control exercises with cognitive targets group
2-face to face Pain education + motor control exercises with cognitive targets group
3-face to face Education sessions for back and lumbar care and common exercises for low back pain group and

common exercises

Main outcome variables

pain; disability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150503022068N4**

Registration date: **2021-08-25, 1400/06/03**

Registration timing: **retrospective**

Last update: **2021-08-25, 1400/06/03**

Update count: **0**

Registration date

2021-08-25, 1400/06/03

Registrant information

Name

amir letafatkar

Name of organization / entity

kharazmi university

Country

Iran (Islamic Republic of)

Phone

+98 21 2225 8084

Email address

amir.letafatkar@khu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-02, 1400/03/12

Expected recruitment end date

2021-07-29, 1400/05/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of online and face-to-face cognitive exercises in people with non-specific chronic low back pain

Public title

Comparison of the effect of online and face-to-face cognitive exercises in people with non-specific chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

At least time for low back pain is 12 weeks and 3 days a week. Pain should be determined at the discretion of a physician and also using the Quebec questionnaire. People are in the medium risk group according to the Start Back tool Score 14% or more on the Oswestry Disability Index Has a pain intensity equal to or greater than 4 on a numerical rating scale The pain is between the last rib and the gluteal Have not taken any new medication or people who do not need medication during the 6 weeks before and while studying Body mass index less than or equal to 30 Women and men 25 to 55 years

Exclusion criteria:

Pregnant women People with a history of lumbar tumors People with inflammatory disease of the spine that is mentioned in their medical history or has been diagnosed by a doctor Participate in exercise therapy courses for the treatment of low back pain in the past year Having any fractures and surgery in the lumbar and dorsal spine

AgeFrom **25 years** old to **55 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **66****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be randomly assigned to 1 of 3 treatments, the samples will be determined in a simple random method using a random number table of Software Allocation Random software. Randomization and allocation sequence for concealment will be done by the person not involved in the research. The ratio of sample allocation will be 1: 1 and will be divided into 2 experimental groups and 1 control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

in this study, the outcome assessor will be blinded of the process of randomization and division of individuals into two experimental groups and control group. Another researcher (blinded to the baseline assessment) will proceed with training according to the group assignment. A blinded outcome assessor who does not know the hypothesis and study methods, measures outcome at baseline and 12 weeks post intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Sports Science Research Institute

Street address

Motahhari St. - Mir Emad St. - Fifth Alley

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2021-08-23, 1400/06/01

Ethics committee reference number

IR.SSRC.REC.1400.082

Health conditions studied**1****Description of health condition studied**

Non specific low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes**1****Description**

pain

Timepoint

Before and after the intervention

Method of measurement

Numerical pain rating scale

2

Description

disability

Timepoint

Before and after the intervention

Method of measurement

Oswestry Disability Index

Secondary outcomes

1

Description

Function

Timepoint

Before and after the intervention

Method of measurement

McGill tests and Luomajoki motor control tests

2

Description

Psychological factors

Timepoint

Before and after the intervention

Method of measurement

Tampa scale- Dass21 questioner- Fear Avoidance Belief Questionnaire- Self-Efficacy Questionnaire- Pain Catastrophizing Scale

3

Description

health status

Timepoint

Before and after the intervention

Method of measurement

Asking questions

Intervention groups

1

Description

Intervention group: 3 online sessions of pain neuroscience education, followed by 15 online sessions of education and exercises of motor control _cognition. The intervention will be done in three phases. The first phase is pain education. Each education session lasts 3 sessions of 30 to 60 minutes for each patient and will be online. In pain education sessions, information about the nature of pain will be targeted to reduce fear avoidance and avoidance beliefs and behaviors, thereby promoting self-efficacy. Also, the training is done using different teaching aids such as pictures and expressing metaphors and examples. The second phase of cognition-targeted motor control training with the aim of recognizing the movements in this stage is designed for different people in the same way. Exercises with at least 10 repetitions and 10 seconds of contraction will be done at home for 2 sets. The third phase is cognition-targeted dynamic and functional exercises with the aim of recognizing.

Becomes. The progress of the exercises goes to the exercises in which the patient feels fear in performing those movements. In this stage, the exercises are designed for each person separately because the feeling of pain is different in each patient and in each activity, and the training of the exercises in this stage will be online. Remind the therapist during all three stages, if necessary, to teach neuroscience. Challenges and reassures patients that the exercise provided is safe. In this group, interventions are done with Skype or Whats App (depending on availability).

Category

Treatment - Other

2

Description

Intervention group: 3 face to face sessions of pain neuroscience education, followed by 15 face to face sessions of education and exercises of motor control _cognition. The intervention will be done in three phases. The first phase is pain education. Each education session lasts 3 sessions of 30 to 60 minutes for each patient and will be online. In pain education sessions, information about the nature of pain will be targeted to reduce fear avoidance and avoidance beliefs and behaviors, thereby promoting self-efficacy. Also, the training is done using different teaching aids such as pictures and expressing metaphors and examples. The second phase of cognition-targeted motor control training with the aim of recognizing the movements in this stage is designed for different people in the same way. Exercises with at least 10 repetitions and 10 seconds of contraction will be done at home for 2 sets. The third phase is cognition-targeted dynamic and functional exercises with the aim of recognizing. Becomes. The progress of the exercises goes to the exercises in which the patient feels fear in performing those movements. In this stage, the exercises are designed for each person separately because the feeling of pain is different in each patient and in each activity, and the training of the exercises in this stage will be face to face. Remind the therapist during all three stages, if necessary, to teach neuroscience. Challenges and reassures patients that the exercise provided is safe.

Category

Treatment - Other

3

Description

Control group: 3 sessions education for back and lumbar care and 15 sessions of common exercises for low back pain. Each education session will last 3 sessions of 30 to 60 minutes. The learning objectives of this training include: Acquiring biomedical knowledge focused on back pain. And 15 sessions of common low back pain exercises will last 30 to 40 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dey physical therapy clinic

Full name of responsible person

Gelareh Alamouti

Street address

No. 5, Sajedi Alley, South Taleghani street

City

Karaj

Province

Alborz

Postal code

3139657435

Phone

+98 26 3355 2745

Email

std_gelarehalamooti@khu.ac.ir

2

Recruitment center

Name of recruitment center

Amin physical therapy clinic

Full name of responsible person

Gelareh Alamouti

Street address

Gol Nabi St.,next to Hosseineh Ershad, Shariati St.

City

Tehran

Province

Tehran

Postal code

1941911371

Phone

+98 21 2289 5767

Email

std_gelarehalamooti@khu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kharazmi University

Full name of responsible person

Amir Letafatkar

Street address

Center for Human Movement Sciences Kharazmi
University Mirdamad, Sout Razan Street, Hesari Street
,Keshvari Sport complex

City

Tehran

Province

Tehran

Postal code

439815875

Phone

+98 21 2222 8001

Email

std_gelarehalamooti@khu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kharazmi University

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

Kharazmy University

Full name of responsible person

Gelareh Alamouti

Position

PhD student

Latest degree

Ph.D.

Other areas of specialty/work

corrective exercises and sport injury

Street address

Center for Human Movement Sciences Kharazmi
University Mirdamad, Sout Razan Street, Hesari Street
,Keshvari Sport complex Tehran, Iran

City

Tehran

Province

Tehran

Postal code

439815875

Phone

+98 21 2222 8001

Email

gelarehalamooti@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Center for Human Movement Sciences Kharazmi
University

Full name of responsible person

Gelareh Alamouti

Position

PhD student

Latest degree

Ph.D.

Other areas of specialty/work

Corrective exercise and sport injury prevention

Street address

Center for Human Movement Sciences Kharazmi
University Mirdamad, Sout Razan Street, Hesari Street
,Keshvari Sport complex Tehran, Iran

City

Tehran

Province

Tehran

Postal code

439815875

Phone

+98 21 2222 8001

Email

gelarehahalamooti@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Center for Human Movement Sciences Kharazmi
University

Full name of responsible person

Gelareh Alamouti

Position

PhD student

Latest degree

Ph.D.

Other areas of specialty/work

Corrective exercise and sport injury prevention

Street address

Center for Human Movement Sciences Kharazmi
University Mirdamad, Sout Razan Street, Hesari Street
,Keshvari Sport complex Tehran, Iran

City

Tehran

Province

Tehran

Postal code

439815875

Phone

+98 21 2222 8001

Email

gelarehahalamooti@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as dependent variables, The
average of all samples, can be shared in scientific
articles.

When the data will become available and for how long

Access period starts 3 months after the results are
published

To whom data/document is available

Personal information is confidential and General
outcomes in paper form Available to everyone.

Under which criteria data/document could be used

General outcomes in paper form Available to everyone.

From where data/document is obtainable

Gelareh Alamouti Phone: 09107161695 Email:
gelarehahalamooti@gmail.com

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

3 months after the publication of the results, the
applicant can have the data by sending an email

Comments