Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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
Age
From **25 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target 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 and12 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
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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
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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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Other areas of specialty/work
corrective exercises and sport injury
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Gelareh Alamouto

Position

PhD student

Latest degree

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Other areas of specialty/work

Corrective exercise and sport injury prevention

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gelarehalamooti@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: gelarehalamooti@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