

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of multimedia training on pain management on the severity of pain, depression and catastrophic in patients with non-specific chronic low back pain.

Protocol summary

Study aim

The Effect of Multimedia Training on Pain Intensity, Depression and Catastrophizing in Patients with Chronic Low Back Pain

Design

Clinical trials with two intervention and blind group, double-blind, control group with parallel, randomized, community-based, and pragmatic groups

Settings and conduct

The researcher will complete the questionnaire by referring to clinics in Fasa. Patients will be randomly assigned into two intervention and control groups. In the multimedia tutorial group, seven cd films will be provided to patients over seven weeks, but face-to-face tutorials will be delivered through lectures, question and answer, and slides. At the end of 7 sessions and one month after the intervention, the questionnaires will be completed again by the patients. No training is given in the control group. This is a double-blind clinical trial.

Participants/Inclusion and exclusion criteria

Including criteria: Age more than 18 years, Chronic lower back pain with expert diagnosis, Depression score higher than 14 Exclusion criteria: Unwillingness to participate in the study, Other chronic underlying diseases

Intervention groups

Multimedia education group and face to face training group

Main outcome variables

Pain intensity; Depression; Catastrophic

General information

Reason for update

Based on a review of recent studies and a recent study done by the research project manager, the researchers have decided to consider catastrophizing and depression as secondary outcomes in the present research project.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180313039074N1**

Registration date: **2018-03-21, 1397/01/01**

Registration timing: **prospective**

Last update: **2022-02-22, 1400/12/03**

Update count: **1**

Registration date

2018-03-21, 1397/01/01

Registrant information

Name

Roghiyeh Firoozian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of multimedia training on pain management

on the severity of pain, depression and catastrophic in patients with non-specific chronic low back pain.

Public title

A survey of multimedia education on severity of pain, depression and catastrophizing in patients with chronic low back pain.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age older than 18 years Possibility to attend face to face face-to-face faculty members Involvement in research on chronic low back pain based on expert diagnosis based on physical examinations and diagnostic tests such as MRI, CT scan and imaging Ability and use of educational CDs in patients with multimedia training Inclination to participate in research Having a depression score higher than 14 according to the Beck Depression Inventory

Exclusion criteria:

Unwillingness or the possibility of continuing to participate in the study for any reason (such as the severity of the pain of the patient), but also to other chronic pain such as chronic headache - chronic psychiatric disorders such as schizophrenia - participation in similar training classes - lack of participation in more than two Educational session

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, patients will be selected by available sampling method. Then, eligible patients will be assigned face-to-face and face-to-face training using random numbers in three groups of multimedia tutorials. As perpendiculars A represent multimedia tutorials, B represents a face-to-face education group and C represents a control group that will have six different modes; for example: (1-AABBcc, 2-ABcABc, ..., 6-ABccBA Then, to select the sample individuals, we move our finger randomly from a random point table in the direction of a row or column. Whenever there are numbers between one and six, the permutation is related to that number. For example, if number 6 arrives, the permutation of the ABCCBA is written down so that qualified patients are placed in three groups of multimedia education, face-to-face and control. The selection of permutations is repeated 15 times, so that 99 patients are assigned to three equal groups

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study blind people will be involved with study participants and analysts who will do the study analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Faculty of Nursing, Fatemiyeh Shiraz

City

shiraz

Province

Fars

Postal code

71345-1978

Approval date

2017-03-28, 1396/01/08

Ethics committee reference number

IR-SUMS.REC.1396.117

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

The average intensity of pain during the last 2 weeks

Timepoint

Before the intervention, immediately after the intervention (7 training sessions) and one month after the intervention

Method of measurement

The average intensity of pain during the last 2 weeks based on the numerical rating scale

Secondary outcomes

1

Description

Average pain catastrophizing score

Timepoint

Before the intervention, immediately after the intervention (7 training sessions) and one month after the intervention

Method of measurement

Pain Catastrophizing Scale

2

Description

Average Depression score

Timepoint

Before the intervention, immediately after the intervention (7 training sessions) and one month after the intervention

Method of measurement

Beck Depression Scale

Intervention groups

1

Description

Intervention group 1: Seven educational films will be provided to patients in seven weeks, which will be watched as a CD in the home. Intervention group 2: Face-to-face training, in which the patients fall into groups of 8 to 10 and receive training for seven weeks.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamza clinic

Full name of responsible person

Dr. Maryam Shayegan

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Nomads Street Hamza Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Maryam Shayegan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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