Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone
+98 71 5331 8075

Email address
r.firooziyan@fums.ac.ir

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 twoEducational 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
Street address
Nomads Street Hamza Clinic
City
Fasa
Province
Fars
Postal code
07153327273
Phone
+98 71 5331 4043
Email
R.firooziyan@fums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Seyed Basir Hashemi
Street address
Shiraz Branch of Zand Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3230 5410
Email
Vcrdep@sums.ac.ir
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
Street address
Shiraz Fatemeh Nursing and Midwifery Faculty
City
Shiraz
Province
Fars
Postal code
71936-13119
Phone
+98 71364742548
Email
R.firooziyan@fums.ac.ir

Person responsible for scientific 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

Street address
Shiraz Namazi Square - Faculty of Nursing and Midwifery of Hazrat Fatemeh

City
Shiraz

Province
Fars

Postal code
71936-13119

Phone
+98 71364742548

Email
shaygan@sums.ac.ir

Person responsible for updating data

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

Street address
Shiraz Namazi Square, Faculty of Nursing and Midwifery, Fatemeh

City
Shiraz

Province
Fars

Postal code
71936-13119

Phone
+98 71364742548

Email
shaygan@sums.ac.ir

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