

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of pain management education on severity of pain, anxiety and disability after lumbar surgery in patients with chronic low back pain referred to hospital

Protocol summary

Study aim

Determining the effect of pain management training on pain intensity, anxiety and disability after the low back pain in patients with chronic low back pain referring to Chamran Hospital in Shiraz,

Design

This study is a parallel controlled clinical trial (RCT) study that examines the effectiveness of pain management training on pain intensity, anxiety and disability in patients undergoing lower back surgery in Chamran Hospital of Shiraz. Patients are divided into intervention and control groups.

Settings and conduct

Sampling was randomly selected from patients eligible for surgery in Chamran Hospital, 70 people. They were randomly assigned to control and intervention groups using randomized software. Chamran Hospital affiliated to Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Individuals aged 70-30. Existing chronic pain more than 3 months before surgery based on expert diagnosis. In the past 8-4 weeks, surgery has been performed on the stenosis of the spinal cord and the intervertebral disk. The possibility of participating in educational interventions based on the opinion of the surgeon. Having at least literacy (reading and writing). Willingness to participate in research and complete informed consent form

Intervention groups

Pain management training is given to patients in the intervention group twice a week during 7 sessions of 60-90 minutes. And the control group receives only routine treatment and does not receive any training.

Main outcome variables

Determine and compare the mean of severity of pain, anxiety, disability before, immediately and 3 months after the intervention in the intervention and control

groups of the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180310039021N1**

Registration date: **2019-03-04, 1397/12/13**

Registration timing: **retrospective**

Last update: **2019-03-04, 1397/12/13**

Update count: **0**

Registration date

2019-03-04, 1397/12/13

Registrant information

Name

Mahsa Zamani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pain management education on severity of pain, anxiety and disability after lumbar surgery in patients with chronic low back pain referred to hospital

Public title

The effect of pain management education on severity of pain, anxiety and disability after lumbar surgery in patients with chronic low back pain

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Individuals aged 70-30. Existing chronic pain more than 3 months before surgery based on expert diagnosis. In the past 8-4 weeks, surgery has been performed on the stenosis of the spinal cord and the intervertebral disk. The possibility of participating in educational interventions based on the opinion of the surgeon. Having at least literacy (reading and writing) Willingness to participate in research and complete informed consent form

Exclusion criteria:

Participate in previous studies Absence in training sessions more than 2 sessions Cases of other chronic diseases unrelated to patient pain Having mental disabilities such as schizophrenia

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method using a random number table so that after determining the exact number of people in the community each is coded in each order. Then, randomly, from a table point in the direction of a row or column, randomly begins choosing by computer

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

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

No.181,10Th Mikhak, Mikhak Ave, Mianrod Town

City

shiraz

Province

Fars

Postal code

7179716974

Approval date

2018-04-11, 1397/01/22

Ethics committee reference number

IR.SUMS.REC.1397.003

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

Spinal cord stenosis and Disk Herniation

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety Score in PASS pain anxiety inventory and Disability score in Oswestry questionnaire and Severity of pain in the numerical scale of pain

Timepoint

Before the intervention begins.After the intervention.Three months later

Method of measurement

Pain Anxiety questionnaire .PASS20 . Oswestry Disability questionnaire. Numerical Scale of Pain

Secondary outcomes

empty

Intervention groups**1****Description**

Patients are divided into two groups: intervention group: Patients in this group receive pain management training at 7 sessions of 60-90 minutes twice a week. It should be noted that the training of the physical activities necessary for the patient will be carried out by a physical therapist and with the advice of the surgeon, based on the type of injury and type of surgery. In each training session, firstly review the contents of the session before

and answer the possible questions of the patients. It will be given. Immediately after the training sessions and three months later, the above questionnaires were completed again .

Category

Lifestyle

2**Description**

Control group: Only routine care is performed without additional work, and the questionnaire is completed first and again 3 months later by the patients in this group.

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

Chamran Hospital affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Syed Ali Hashemi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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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

50

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

Maryam Shaygan

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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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

Confidentiality of patient information

Study Protocol

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

Statistical Analysis Plan

Not applicable

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