

# 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)

##### Phone

+98 71 3840 2412

##### Email address

zanimah@sums.ac.ir

##### 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

**Street address**

Chamran Blvd

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Chamranhosp@sums.ac.ir

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Ali Bahador

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Zand Ave

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۷۱۳۳۶ - ۷۱۳۴۸

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**Email**

president@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**

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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nursing school.Namazai Square.Zand Street

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Shiraz University of Medical Sciences

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
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Mahsa Zamani  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
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**Province**  
Fars  
**Postal code**

## 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