

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of pain management education on pain intensity and disability of elderly people with post traumatic lower extremity pain after surgery

Protocol summary

Study aim

The effect of pain management education on pain and disability and trauma to the lower extremities after surgery

Design

Two blind clinical trials, in which 75 patients were randomly assigned to control and intervention

Settings and conduct

Hospitals affiliated to Shiraz University of Medical Sciences. The study is conducted as pain management training in the intervention group. The surgeon, the physiotherapist, and the results analyst individual will not be aware of any patient grouping in the study.

Participants/Inclusion and exclusion criteria

Entry requirements Aged 50 to 74 years, acute lower limb pain less than 8 weeks, patients undergoing orthopedic surgery. The company is undergoing intervention according to the surgeon's physician. Having at least literacy. Conditions of failure to enter The patient's unwillingness to continue to participate in the study, the occurrence of an unplanned physical and emotional problem during the intervention, participation in previous studies, absenteeism in more than 2 sessions, chronic illnesses and psychosocial disabling diseases, Having lower limb pain before surgery, fracture and severe damage to other parts of the body due to trauma

Intervention groups

The control group only received physiotherapy Patients in the intervention group receive psychosocial interventional pain management in addition to physical therapy. Training includes (managing pain and preventing pain, pain control and stress management, positive thinking, decisiveness, communicating). 2 sessions per week are held in lectures. The questionnaire is trained by both groups before, one month and three months after training.

Main outcome variables

Proper management of pain; prevention of chronicity and

persistence of pain and for use in future studies.

General information

Reason for update

Due to some problems for researchers and difficulty in finding samples, sampling has been delayed. Also, to facilitate sampling, the age range of participants changed. Therefore, the mentioned information has been updated.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180307038984N1**

Registration date: **2018-09-03, 1397/06/12**

Registration timing: **prospective**

Last update: **2022-05-30, 1401/03/09**

Update count: **1**

Registration date

2018-09-03, 1397/06/12

Registrant information

Name

Fatemeh Bygom Moosavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2020-08-01, 1399/05/11

Actual recruitment end date

2020-11-30, 1399/09/10

Trial completion date

2020-11-30, 1399/09/10

Scientific title

Effect of pain management education on pain intensity and disability of elderly people with post traumatic lower extremity pain after surgery

Public title

Effect of pain management education on pain in elderly people with post traumatic lower extremity pain after surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

people of 50 to 74 years old Patients with acute lower limb pain are their most severe pain. Despite lower extremity pain less than 8 weeks old. Patients with post-traumatic lower extremity orthopedic surgery have been created. The conditions of participation in the intervention, according to an orthopedic doctor Having at least a literacy

Exclusion criteria:

Unwillingness to continue participating in the study Occurrence of unhealthy physical and emotional problems during intervention Participate in previous studies Absence in training sessions more than 2 sessions Disabling physical illness such as spinal cord injury, chronic pain, MS and ... The development of psychosocial disabilities such as schizophrenia and cognitive disorders. Patients who have had lower extremity before trauma Patients suffering from trauma suffer severe damage to other parts of the body, except the lower extremities.

AgeFrom **50 years** old to **74 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **82**Actual sample size reached: **75****Randomization (investigator's opinion)**

Randomized

Randomization description

Block Randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Failure to inform the surgeon, physiotherapist and one analyst, grouping patients

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

Central Building of Shiraz University of Medical Sciences, Zand st

City

shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Approval date

2018-06-20, 1397/03/30

Ethics committee reference number

IR.SUMS.REC.1397.266

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

Fracture of lower leg, including ankle

ICD-10 code

S82

ICD-10 code description

شکستگی اندام تحتانی، از جمله مچ پا

Primary outcomes**1****Description**

Disability and Pain

Timepoint

Before the study begins; One month and three months after the study

Method of measurement

Pain scale inventory and Rowland and Maurice Physical Disability Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group: Pain management training in 6 sessions (weekly 2 sessions of 45-60 minutes in a lecture), along with physiotherapy, to 41 elderly patients with lower limb trauma. The training includes: (Pain Management Training; Definition pain and prevent chronic pain, determination, positive thinking skills, effective communication, stress management and anger) is. The questionnaires are completed before and after training one month and three months later by intervention and control group. "Control group:" Only physiotherapy is received.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals Affiliated to Shiraz University of Medical Sciences

Full name of responsible person

fetmeh mousavi

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Web page address

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

Maryam Shaygan

Position

Associate professor,PHD

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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

Article.Thesis

When the data will become available and for how long

Unlimited

To whom data/document is available

Public

Under which criteria data/document could be used

Field of treatment

From where data/document is obtainable

Author

What processes are involved for a request to access data/document

E-mail Request by Email - Visit the university's electronic source

Comments

-

Person responsible for updating data**Contact****Name of organization / entity**

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