

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of training and telenursing on the low back pain and disability of patients after Lumbar spine surgery

Protocol summary

Study aim

Determining the effect of training and tele-nursing on the low back pain and disability of patients after Lumbar spine surgery

Design

Parallel group randomized trial in which participants will be divided into two groups by permuted block randomization. Sample size was calculated 72.

Settings and conduct

After referring to the neurosurgery department of 5 Azar Hospital in Gorgan, based on the admission criteria, patients who are candidate for lumbar spine surgery will be selected. After assigning informed consent, the patients will be divided into two groups based on block randomization method. Before surgery and then after surgery, at the time of discharge, the questionnaires will be completed by the participants of the both groups. After discharging from the hospital, the intervention group will receive educational multimedia through social media software twice a week during the first month and then once a week in the second month. Additionally the researcher will follow up the condition of the patients by phone call once a week. The control group will also receive routine care and education. The studied variables will be measured once at the end of the first month and second time at the the end of month 2 in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients between 18 and 64 years old, who have undergone lumbar spine surgery, speak in Persian and have the ability to use social communication software. Exclusion criteria: non-cooperation, comorbidity, pregnancy

Intervention groups

For the intervention group after discharge from the hospital, educational multimedia will be sent individually through social communication software twice a week in the first month, and then once a week in the second month.

Main outcome variables

pain, Disability caused by back pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190727044347N5**

Registration date: **2022-12-11, 1401/09/20**

Registration timing: **prospective**

Last update: **2022-12-11, 1401/09/20**

Update count: **0**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name

Fatemeh Shirazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4254

Email address

shirazifa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of training and telenursing on the low back pain and disability of patients after Lumbar spine surgery

Public title

The effect of training and telenursing on the low back pain and disability of patients after Lumbar spine surgery

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of lumbar disc herniation, spinal stenosis or lumbar spondylolisthesis leading to surgery by a physician Lumbar disc herniation surgery during last week Interest in participating in the study Age between 18 and 64 years Ability to read, write and speak in Persian The ability to use a smart mobile phone and access to the Internet

Exclusion criteria:

Associated diseases such as musculoskeletal diseases Having rheumatoid arthritis or ankylosing spondylitis Pregnancy

Age

From **18 years** old to **64 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be divided into two control and intervention groups (training and tele-nursing) using random allocation with permutation block method. Then participants will be assigned to two intervention and control groups by using Random Allocation software for randomization in 12 blocks, each block with a size of 6 people.

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2022-10-08, 1401/07/16

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1401.080

Health conditions studied

1

Description of health condition studied

patients after Lumbar spine surgery

ICD-10 code

G54.4

ICD-10 code description

Lumbosacral root disorders, not elsewhere classified

Primary outcomes

1

Description

pain

Timepoint

before surgery, during discharge, one month after the intervention and two months after the intervention

Method of measurement

visual analog scale pain

2

Description

Disability caused by back pain

Timepoint

before surgery, during discharge, one month after the intervention and two months after the intervention

Method of measurement

Oswestry low back pain disability questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group after discharge from the hospital, educational multimedia will be sent individually through social communication

software twice a week in the first 4 weeks and then once a week in the second 4 weeks. Multimedia includes text, audio, video and images, which patients use their visual and auditory senses to learn. The educational content includes necessary information regarding the surgery and the need for rehabilitation, pharmaceutical (according to the doctor's prescription) and non-pharmacological pain control methods, counseling to improve the mental and emotional state, advice regarding proper nutrition, the amount and type of activity allowed in each week, sports exercises and the use of assistive devices, and daily self-care activities (How to sit and get up, bath, toilet, etc.). The participants are requested to study the educational materials during the week and apply those materials in their daily life. Additionally the researcher will follow up the condition of the patients by phone call once a week. The control group will also receive routine care and education. The studied variables will be measured once at the end of the first month and second time at the the end of month 2 in both groups.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar Educational and Therapeutic Center, Gorgan

Full name of responsible person

Mehri Mahdavi

Street address

6th Azar Ave.,5 Azar St

City

Gorgan

Province

Golestan

Postal code

4917761551

Phone

+98 17 3222 0561

Fax

+98 17 3222 8363

Email

pr-5azar@goums.ac.ir

Web page address

https://goums.ac.ir/index.php?slc_lang=fa&sid=104

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vahid Hosseini

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 7282 3235

Fax

+98 71 7594 3230

Email

vcrdep@sums.ac.ir

Web page address

<https://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

Fatemeh Shirazi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery (SA), Namazi Square, Namazi Hospital

City

Shiraz

Province

Fars

Postal code

7193613119

Phone

+98 71 3647 4254

Email

shirazi_1393@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Shirazi

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Person responsible for updating data

Contact

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable