

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Study of the effect of gentle stretching exercises and foot reflexology massage on the pain of patients after spinal surgery

#### Protocol summary

Study of the severity of pain in the lower limbs and the back in patients ,after spinal surgery

#### Study aim

Effect of gentle exercises and foot reflexology massage on pain after spinal surgery

#### Design

This study was a randomized clinical trial with a control group with parallel, one-blind, randomized groups. Patients were entered on the basis of inclusion criteria and are randomly assigned to the control or intervention group 1 and 2 using closed envelopes

#### Settings and conduct

Patients undergoing thoracic and lumbar spine surgery according to entry criteria are randomly divided into two intervention groups and one control group. The day before surgery, the demographic and medical characteristics of the patient were completed and pain intensity was recorded using the visual scale of the pain. Intervention in group 1 on the day after surgery is reflexology massage of the foot of the foot that continues after discharge three times a week for 6 weeks. In group 2, tensile training begins on the day after surgery, which is performed in the lining or sitting room for half an hour during the hospitalization period and 3 times a week for 6 weeks in the discharge period. In the control group, only routine medications and care are performed. The severity of pain in patients was measured and recorded in all three groups before surgery, the first day after surgery, discharge time and then one week and six weeks later using the visual scale.

#### Participants/Inclusion and exclusion criteria

-Aged 65-18 years old - Complete lack of sensory and motor impairment in the lower extremities - Nervous musculoskeletal disorders - No scarring, fractures and skin disorders in the legs - No alcohol and other drugs - No limitation of movement in the foot - Failure to develop malignant diseases

#### Intervention groups

Group 1: Soft stretching exercises Group 2: Foot reflexology

#### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180404039194N1**

Registration date: **2018-08-19, 1397/05/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-19, 1397/05/28**

Update count: **0**

##### Registration date

2018-08-19, 1397/05/28

##### Registrant information

##### Name

Ommolbanin Rostami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3341 9914

##### Email address

rostamio1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2018-12-22, 1397/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Study of the effect of gentle stretching exercises and foot reflexology massage on the pain of patients after spinal surgery

**Public title**

Study of the effect of gentle stretching exercises and foot reflexology massage on the pain of patients after spinal surgery

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients with thoracic and lumbar spine surgery  
Complete lack of sensory and motor impairment in the lower extremities of patients who have had spine surgery  
Satisfaction with co-operation during admission and continuation at home  
Lack of inflammatory and vascular diseases, such as arthritis and vascular thrombosis  
Absence of musculoskeletal disorders  
Lack of ulcers, fractures and skin disorders in the legs  
Lack of alcohol and other drugs  
Lack of limb movement in the lower extremity  
Not pregnant  
Non-malignant diseases  
Being trained or accompanying  
Age of 16-70 years

**Exclusion criteria:**

Lack of spinal surgery  
Sensory and motor disorder, complete or incomplete in lower limbs  
Any wounds in the foot  
Incompetent the patient or accompany of her or him

**Age**

From **16 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Assigned with random spss numbers, in intervention or control groups, randomly

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients who have spinal surgery have undergone surgery or intervention according to entry criteria and randomly in the control group or intervention group 1 or 2. Patients in each group are unaware of being in the intervention or control group. However, in each group patients are told about routine or intervention (reflexology or stretching exercises) and they will intervene in case of written consent.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

regional research ethics committee Mashhad  
University of Medical Sciences

**Street address**

Medical-Surgical Department, Nursing and Midwifery  
School, Ebnesina Street, Doctra Crossroad, Mashhad,  
Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Approval date**

2018-06-30, 1397/04/09

**Ethics committee reference number**

IR.MUMS.REC.1397.084

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

Severity of pain after surgery of the thoracic sphincter  
and lumbar spine

**ICD-10 code**

G54

**ICD-10 code description**

Nerve root and plexus disorders

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

Severity of pain after surgery of the thoracic sphincter  
and lumbar spine

**Timepoint**

Measuring the severity of pain in patients using the  
visual scale of pain in the day before surgery, the day  
after surgery, one week and 6 weeks after surgery in  
person or through telephone follow up or patient referral  
to the clinic of the studied hospitals

**Method of measurement**

Measuring the pain intensity of patients using the visual  
scale of pain

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group 1: The intervention is performed as a reflexology massage on the sole of the palm, with the thumb, on the inner curvature of the floor of both legs, the alternating to the wave and smoke, and in the reciprocation of about 10 -7 minutes per foot. This intervention is performed at least once a day, 3 times a week and for 6 weeks.

#### Category

Rehabilitation

### 2

#### Description

Intervention group:

#### Category

Rehabilitation

### 3

#### Description

Control group:

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emdadi Shahid Kamyab hospital, Ghaem hospital, Hasheminejad hospital

##### Full name of responsible person

Mahmood Bakhshi

##### Street address

Emdadi Hospital, Fadaeiyan Eslam Street, Nakhrisi Intersection

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9166637477

##### Phone

+98 51 3859 2121

##### Fax

+98 51 3854 9234

##### Email

skh@mums.ac.ir

##### Web page address

<http://h-kamyab.mums.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Ghaem hospital

#### Full name of responsible person

Bakhshi Mahmood

#### Street address

Qa'im Hospital, Dr Ali Shariati Square, Beginning at Ahmadabad Street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

99199-91766

#### Phone

+98 51 3840 0000

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+98 51 3845 3239

#### Email

[Quaem.Medical.Center@mums.ac.ir](mailto:Quaem.Medical.Center@mums.ac.ir)

#### Web page address

<http://quaem.mums.ac.ir/>

### 3

#### Recruitment center

##### Name of recruitment center

Hasheminejad hospital

##### Full name of responsible person

Mahmood Bakhshi

##### Street address

Mashhad, Shahid Mofatheh-end of Abu Ravihan Blvd.

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913791336

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##### Web page address

<http://hasheminejad.mums.ac.ir/index.php>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Tafaghodi

##### Street address

Faculty of Nursing and Midwifery, Ebne Sina Ave., Doktora Intersection, Mashhad, Iran

##### City

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##### Province

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##### Postal code

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+98 51 3854 3031

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Bakhshim@mums.ac.ir

**Web page address**

http://nurse.mums.ac.ir/

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Ommolbanin Rostami

**Position**

Senior of Surgical Medical Nursing Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Ebne Sina Ave., Doktora Intersection, Mashhad, Iran

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**Email**

rostamio1@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Ommolbanin Rostami

**Position**

Master of nursing|(medical,surgical)

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No,22,Hedayat 5 Ave.,Fadaeiyan 18 Blvd.,Mashhad Town

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**Province**

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**Email**

rostamio1@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Ommolbanin Rostami

**Position**

Senior of Surgical Medical Nursing Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Faculty of Nursing and Midwifery, Ebne Sina Ave., Doktora Intersection, Mashhad, Iran

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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**

The effect of mild stretching exercises and foot reflexology massage on the severity of pain in the lower and lower extremities in patients undergoing thoracic and lumbar spine surgery. The results of this research are shared among other researchers in this regard.

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Researchers and patients candidate for spinal surgery

**Under which criteria data/document could be used**

Data analysis will be done using descriptive and inferential statistics. After collecting data and encoding and logging into the computer, spss 11 will be used for analysis. To describe the data, the frequency distribution

table (for qualitative variables) and the mean and standard deviation (for quantitative variables) will be used. In the analytical statistics, first, a quantitative quantitative test of normal values using Kolmogorov-Smynov and Shapiro Wilk tests. To determine the homogeneity of data in three groups, the Chi-square or Fisher test for qualitative variables and the Kruskal-Wallis test will be used for quantitative variables in case of normalization. Also, intra-group comparisons will be used based on whether data are normal or not. Friedman test variance analysis will be used. To determine the relationship between underlying and intervention variables, three groups of two-way ANOVA tests will be used. For all tests, the confidence coefficient will be 95%.

**From where data/document is obtainable**

Faculty of Nursing and Midwifery, Ibn Sina Avenue, Doktora st. Mashhad, Iran Phone: 0098 5138591511 Fax: 0098 5138597313 Zip Code: 9137913199 E-mail: NMS.IT@mums.ac.ir

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

Referring to the library of Mashhad Nursing and Midwifery Faculty and presenting the identification card to this unit and receiving the existing documentation.

**Comments**