

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparison of the effect of reflexology and spiritual care on pain severity, anxiety, sleep quality and coping strategies of patients with chest trauma

Protocol summary

Study aim

Comparison of the effect of reflexology and spiritual care on pain severity, anxiety, sleep quality and coping strategies of patients with chest trauma.

Design

A single-center double blinded randomized controlled trial, without placebo.

Settings and conduct

This study will be conducted on 80 patients with chest trauma, hospitalized at Modarres Hospital of Saveh.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Multiple trauma patients with blunt and penetrated chest trauma based on injury severity score; communicating skills; complete consciousness after surgery; belief to the religion of Islam; willingness to cooperate in the study and sign the informed consent form; not having skin disease with the feet involvements; not having diabetes with peripheral nerve involvement and sensory disorders in the feet; not having acute infections or ulcers in the feet; 18 to 65 years old patients. Exclusion criteria: Unwillingness to cooperate in the study; experience of spirituality counseling classes for the past 6 months to a year; past year's crisis situations (divorce, death of close relatives and serious accidents)

Intervention groups

First intervention group: In the first intervention group, reflexology will be performed at a slowly, with a regular rhythm and with a depth of 1 to 3 mm for 3 consecutive days. Second intervention group: In the second intervention group, the samples will receive spiritual care in groups of 4 to 6 peoples. The educational content will be held in three 45-minute session in the Surgery Department training room in 3 days, with a day interval.

Main outcome variables

Severity of pain; severity of anxiety; quality of sleep; adaptation strategy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161223031522N12**

Registration date: **2019-11-02, 1398/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-02, 1398/08/11**

Update count: **0**

Registration date

2019-11-02, 1398/08/11

Registrant information

Name

Vahid Naseri Salahshour

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 3417 3505

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-01, 1398/08/10

Expected recruitment end date

2019-12-31, 1398/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of reflexology and spiritual care on pain severity, anxiety, sleep quality and coping strategies of patients with chest trauma

Public title
The effect of reflexology and spiritual care on pain, anxiety, sleep quality and adaptation of patients with chest trauma

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Multiple trauma patients with blunt and penetrated chest trauma based on injury severity score. Communicating skills. Complete consciousness after surgery. Belief to the religion of Islam. Willingness to cooperate in the study and sign the informed consent form. Not having chronic pain (migraine headaches, low back pain, sciatica pain, rheumatic pain, arthritis pain, etc.). No skin disease with feet involvements. Not having diabetes with peripheral nerve involvement and sensory disorders in the feet. Not having acute infections or ulcers in the feet. Not having coagulation disorders. 18 to 65 years old patients.
Exclusion criteria:
Unwillingness to cooperate in the study. Experience of spirituality counseling classes for the past 6 months to a year. Past year's crisis situations (divorce, death of close relatives and serious accidents).

Age
From **18 years** old to **65 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples divided into first and second intervention groups using simple random allocation. In this study, a dice will be used as randomization tool and for making the sequences the paired numbers will be assigned to the first intervention group and the odd numbers will be assigned to the second intervention group.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study is a double-blinded study in which the data analyzer and the participants did not know the random allocation in the first and second intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences
Street address
South Sheikh Bahaei Ave., Mollasadra St., Vanak Sq.
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2019-10-15, 1398/07/23
Ethics committee reference number
IR.BMSU.REC.1398.206

Health conditions studied

1

Description of health condition studied
Chest trauma
ICD-10 code
S29.7
ICD-10 code description
Multiple injuries of thorax

Primary outcomes

1

Description
Severity of pain based on visual analogue scale
Timepoint
Before and after intervention
Method of measurement
visual analogue scale

2

Description
Anxiety score in Spielberger inventory
Timepoint
Before and after intervention
Method of measurement
Spielberger anxiety inventory

3

Description

Sleep quality score in Pittsburgh index

Timepoint

Before and after intervention

Method of measurement

Pittsburgh sleep quality index

4

Description

Adaptation score in Lazarus and Folkman's questionnaire

Timepoint

Before and after intervention

Method of measurement

Lazarus and Folkman's adaptation questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: in the first intervention group, reflexology will be performed at a slowly, with a regular rhythm and with a depth of 1 to 3 mm for 3 consecutive days.

Category

Lifestyle

2

Description

Second intervention group: in the second intervention group, the samples will receive spiritual care in groups of 4 to 6 peoples. The educational content will be held in three 45-minute session in the Surgery Department training room in 3 days, with a day interval.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres Hospital

Full name of responsible person

Elham Farhadi

Street address

Modarres Hospital, Motahhari St., Azadi Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Gholamhosein Alishiri

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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

Bagheiat-allah 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

Arak University of Medical Sciences

Full name of responsible person

Vahid Naseri-Salahshour

Position

MSc. of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

36 months after the publishing of the results.

To whom data/document is available

Researchers in academic and scientific institutions.

Under which criteria data/document could be used

Scientific purposes.

From where data/document is obtainable

Vahid Naseri-Salahshour vahidnaseri1994@yahoo.com

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

2 to 3 working days.

Comments