

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### A comparative study of reflexology and reflexology with aromatherapy on chronic low back pain and mood of female operating room staff

#### Protocol summary

back pain and mood

##### Study aim

Comparison of reflexology and reflexology with aromatherapy on chronic low back pain and mood of female operating room staff

##### Design

Clinical trial will be conducted in three groups, double blind, randomized, phase three on 105 people, randomization by minimization method using mini-foot software. Groups: reflexology with lavender oil, Reflexology without lavender oil and control group

##### Settings and conduct

The researcher will do his research in the operating room. The intervention will be performed for 9 sessions over 4 months. In the intervention group, reflexology treatment without lavender oil, simple and superficial massage (superficial stroke) for 2 minutes, general reflexology therapy for 18 minutes and then 5 minutes of specialized reflexology in the sole of the foot. In the lavender oil reflection therapy intervention group, a drop of lavender oil is poured on a non-absorbable tissue and attached to the subject's collar with a pin, and the person inhales the lavender oil while receiving reflection therapy. There will be no intervention in the control group.

##### Participants/Inclusion and exclusion criteria

Have the satisfaction of participating in the study, have chronic low back pain, have organ health in the legs, have no history of allergies to herbs

##### Intervention groups

In the intervention group, lavender oil-free reflexology, simple massage for 2 minutes, general reflexology for 18 minutes and then 5 minutes of specialized reflexology. In the lavender oil reflection therapy intervention group, a drop of lavender oil is poured on a non-absorbable tissue and attached to the subject's collar with a pin, and the person inhales the lavender oil while receiving reflection therapy. There will be no intervention in the control group.

##### Main outcome variables

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210908052405N1**

Registration date: **2021-09-25, 1400/07/03**

Registration timing: **prospective**

Last update: **2021-09-25, 1400/07/03**

Update count: **0**

##### Registration date

2021-09-25, 1400/07/03

##### Registrant information

##### Name

Zahra shafiei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 2901

##### Email address

shafieiznm@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-26, 1400/07/04

##### Expected recruitment end date

2022-01-24, 1400/11/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

A comparative study of reflexology and reflexology with aromatherapy on chronic low back pain and mood of female operating room staff

### Public title

A comparative study of reflexology and reflexology with aromatherapy on chronic low back pain and mood of female operating room staff

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Having complete satisfaction with participating in the study Have chronic low back pain based on a specialist doctor's diagnosis. Participants do not have acute pain or need surgery. Have organ health in the feet, especially the soles of the feet. No history of allergies to medicinal plants

#### Exclusion criteria:

Reluctance of research units to continue participating in the study Allergies to used oils Suffering from mental and emotional trauma

### Age

No age limit

### Gender

Female

### Phase

3

### Groups that have been masked

- Outcome assessor
- Data analyser

### Sample size

Target sample size: **105**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this research, the units under study are selected by convenient sampling. In this way, all the people who meet the inclusion criteria are selected and then the substitution in the groups will be done randomly by the minimization method using the mini-foot software. According to the parameters that we define for the software, the research unit is divided into three groups so that there will be at least a difference between them. In this way, after the selection, the subject is given a unique code that indicates the study group and in their questionnaire, it will be stated that 35 subjects based on the minimization list in the reflection therapy group, 35 subjects in the reflection therapy group Along with aromatherapy, 35 subjects will be in the control group. In this study, minimization will be performed based on parameters such as age, marital status, employment status, duration of low back pain.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Blinding will be such that both the statistical consultant and the questioner will not be aware of the type of

intervention in the units under study. The questionnaire will be distributed by the researcher and completed by the research units.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Faculty of Nursing, Management and Rehabilitation - Isfahan University of Medical Sciences (Research

##### Street address

Hezar Jarib Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8177914716

#### Approval date

2021-09-20, 1400/06/29

#### Ethics committee reference number

IR.MUI.NUREMA.REC.1400.056

## Health conditions studied

### 1

#### Description of health condition studied

Low back pain

#### ICD-10 code

M51.9

#### ICD-10 code description

Intervertebral disc disorder, unspecified

## Primary outcomes

### 1

#### Description

"Low back pain score in McGill Pain Questionnaire" and "Numerical pain scale (10 cm line of pain)"

#### Timepoint

Before the intervention, four months after the intervention

#### Method of measurement

The "McGill Pain Questionnaire" and the "Numerical Pain Scale (10 cm line)" will be used to "measure low back pain".

## 2

### **Description**

"Mood status score in mood profile questionnaire"

### **Timepoint**

Before the intervention, four months after the intervention

### **Method of measurement**

The mood profile questionnaire is used to assess mood.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Lavender oil-free reflexology intervention group: Before the intervention, the patient's low back pain is measured by the questioner using the McGill Pain Questionnaire and the numerical pain scale. The intervention is immediate (three times a week), one month later (three times in Week) and then three months later (three times a week) for a total of 9 sessions over 4 months. The researcher will conduct his research in the room that will be considered in the operating room, all the units will be given a disposable towel and shampoo for washing the feet and a disposable sheet. Before starting the massage, the subjects will wash their feet with body wash shampoo and dry them with a towel. To begin the massage technique, the person will first lie on their back and a pillow will be placed under their head to facilitate the intervention, and then the patient's pants will rise to the knee and the researcher will be in front of the patient. First, the feet will be examined for lumps, pain, tenderness, and any dryness or swelling. Then a simple and superficial massage (superficial stroke) is given for 2 minutes, which is a relaxation technique and will relax the foot and prepare for a specific reflexology treatment. First, a general reflexology will be used for 18 minutes on all reflex points in the sole of the foot and then 5 minutes of specialized reflexology. These points include the solar plexus, the pituitary gland, and the heart, each of which will be massaged with a thumb and constant pressure. The rest of the soles of the feet and some parts of the feet will be massaged continuously on the reflection points without interrupting contact with the skin, using the thumbs or other toes. The external side and sole of the foot will be massaged for one to two minutes each. The massage is performed under the toes with the movements of the thumb and in an arched shape from left to right for one to two minutes, which includes points related to the heart, lungs and chest. Then the rest of the time will be devoted to massaging the points related to the lumbar region in the arched part of the inner side of the foot. The index and middle fingers are used, which will be placed on the reflex points. The fingers will be far apart and close, and a movement similar to a tree worm will be performed on reflex points.

#### **Category**

Treatment - Other

## 2

### **Description**

Control group: There will be no intervention in the control group, but a gift will be considered for them to participate in the research.

### **Category**

Other

## 3

### **Description**

Lavender oil reflexology intervention group: Before the intervention, the person's low back pain is measured by the questioner using the McGill pain questionnaire and the numerical pain scale. The intervention is immediate (three times a week), one month later (three times in Week) and then three months later (three times a week) for a total of 9 sessions over 4 months. This group will be evaluated for sensitivity to lavender oil (by testing skin patches) by rubbing a drop of oil on the inside of the wrist, then examining the signs of allergies after two minutes to be excluded in case of allergies. The researcher will conduct his research in the room that will be considered in the operating room, all the units will be given a disposable towel and shampoo for washing the feet and a disposable sheet. Before starting the massage, the subjects will wash their feet with body wash shampoo and dry with a towel. Pour a drop of lavender oil on an unabsorbable napkin and attach it to the subject's neck with a pin, and the person will receive a reflection. Therapy also inhales lavender oil at the same time. This oil is a greenish-yellow liquid and is obtained by distilling the flowers and flowering branches of the lavender plant, and each drop of it is equivalent to 28 grams of the plant, which is prepared by Baric Essential Pharmaceutical Company. To begin the massage technique, the person will first lie on their back and a pillow will be placed under their head to facilitate the intervention, and then the patient's pants will rise to the knee and the researcher will be in front of the patient. First, the feet will be examined for lumps, pain, tenderness, and any dryness or swelling. Then a simple and superficial massage (superficial stroke) is given for 2 minutes, which is a relaxation technique and will relax the foot and prepare for a specific reflexology treatment. First, a general reflexology will be used for 18 minutes on all reflex points in the sole of the foot and then 5 minutes of specialized reflexology. These points include the solar plexus, the pituitary gland, and the heart, each of which will be massaged with a thumb and constant pressure. The rest of the soles of the feet and some parts of the feet will be massaged continuously on the reflection points without interrupting contact with the skin, using the thumbs or other toes. The external side and sole of the foot will be massaged for one to two minutes each. The massage is performed under the toes with the movements of the thumb and in an arched shape from left to right for one to two minutes, which includes points related to the heart, lungs and chest. Then the rest of the time will be devoted to massaging the points related to the lumbar region in the arched part of the inner side of the foot. The index and middle fingers are used, which

will be placed on the reflex points. The fingers will be far apart and close, and a movement similar to a tree worm will be performed on reflex points.

**Category**

Treatment - Drugs

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**Recruitment centers****1****Recruitment center****Name of recruitment center**

Al-Zahra Hospital in Isfahan

**Full name of responsible person**

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**2****Recruitment center****Name of recruitment center**

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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**

Esfahan University of Medical Sciences

**Proportion provided by this source**

10

**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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Zahra shafiei

**Position**

Instructor, faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Operating room

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
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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

All personal data of study participants are potentially shared after unidentifiable individuals.

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

Access period starts 6 months after the publication of the results, ie from 26/8/2022

### To whom data/document is available

Researchers working in academic institutions

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

Just to study and get acquainted with the research process

### From where data/document is obtainable

The first researcher, Zahra Shafiei,  
shafieiznm@gmail.com

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

Give the request letter to the researcher's email and then send the request items by the researcher within a week

### Comments