Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

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
back pain and mood

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

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Iran (Islamic Republic of)

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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
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Province
Isfehan

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

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital in Isfahan
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
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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
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