Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation of the effect of Tuina-therapy with chamomile oil extract on the intensity of low back pain in the women operating room

Protocol summary

Study aim
Determining the effect of tuinatherapy with chamomile oil extract on the severity of back pain in operating room personnel of selected hospitals in Isfahan city in 2021

Design
This study will be conducted in the form of a randomized, double-blind, controlled clinical trial and will be divided into three groups, A.B.C.

Settings and conduct
This study was conducted in two selected hospitals where the operating room personnel of one hospital will be considered as the control group and the personnel of the other hospital will be considered as the intervention group. In the intervention group, the researcher, at the beginning of the morning shift, appeared in the operating room of the selected hospitals and after additional explanations about the work process, asked the research unit to sit on the bed and in a separate room (rest room for female personnel)) and lie in a comfortable position on his stomach (without seeing the used oil in order to establish the condition of blinding) in the conditions of privacy.

Participants/Inclusion and exclusion criteria
Pregnancy in the last 6 months Suffering from underlying diseases such as rheumatism and diabetes History of back trauma

Intervention groups
Group A: Intervention group one: Tuinatherapy with liquid oil + chamomile plant oil extract Group B: Intervention group two: Tuinatherapy with only liquid oil Group C: Control group

Main outcome variables
Operating room personnel, in order to reduce or improve back pain following long standing in operating rooms, use tuinatherapy using chamomile oil extract as a low-complication drug, instead of chemical drugs with known complications. put in the agenda of their daily use.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220725055548N1**
Registration date: **2022-08-31, 1401/06/09**
Registration timing: **prospective**

Last update: **2022-08-31, 1401/06/09**
Update count: **0**

Registration date
2022-08-31, 1401/06/09

Registrant information

Name
Seyedehmaryam Seyedy

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
2022-09-21, 1401/06/30

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of Tuina-therapy with chamomile oil extract on the intensity of low back pain in the women operating room

Public title

Evaluation of the effect of Tuina-therapy with chamomile on the intensity of low back pain in the women operating room

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Informed consent to participate in the study Absence of cuts, wounds and scratches on the skin of the waist area Female gender (according to the principle of conformity in medical ethics) Having a bachelor's or associate's degree in the operating room Playing the role of circular or scrub Body mass index less than 30 kg/m2 Job-related back pain (based on the individual's history)

Exclusion criteria:

Age

From **25 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization method was used. In this method, 3 blocks containing 35 people in each block are used, and the number of people assigned to each group is equal to 35 people. In this method, blocks are formed based on the variables in question, and half of the intervention people and half of the control people are included in each block.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted in the form of a double-blind randomized clinical trial study. Sampling will be done in an easy or accessible way; In this way, from among the people who meet the criteria for entering the study, from the time the plan is approved until the desired sample size is reached, people are entered into the study; In clearer words, among the female operating room technicians (scrub, circular) working in the operating rooms, after stating the objectives of the study and obtaining informed consent, in the order of access until reaching the target sample size (105 people), people will be included in the study. Then, people will be divided into three groups by simple random method.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Hazar Jarib Street Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

7346181746

Approval date

2022-07-17, 1401/04/26

Ethics committee reference number

IR.ARI.MUI.REC.1401.126

Health conditions studied

1

Description of health condition studied

Back pain of female staff in the Operating room

ICD-10 code

Z68.52

ICD-10 code description

Body mass index (BMI) pediatric, 5th percentile to less than 85th percentile for age

Primary outcomes

1

Description

The score of back pain in the Visual Analogue Scale questionnaire and the percentage of people whose questionnaire score is less than 8

Timepoint

Once before the start of the intervention and once again after the end of the intervention

Method of measurement

Visual Analogue Scale standard questionnaire demographic information questionnaire

Secondary outcomes

1

Description

Back pain reduction Score.

Timepoint
Before the start of the intervention and after the end of the intervention or after 10 Massage sessions.
Method of measurement
Visual Analogue Scale questionnaire

Intervention groups

1

Description
Intervention group one: Tuina therapy with liquid oil + chamomile plant oil extract (35 people)
Category
Prevention

2

Description
Intervention group two: Tuinatherapy with only liquid oil (35 people)
Category
Placebo

3

Description
Control group: No specific intervention is performed.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
AlZahra Hospital and Kashani Hospital of Isfahan
Full name of responsible person
Afsana Amini Bitraf and Habib Jalali
Street address
Isfahan Sefe Blvd AlZahra (S) Educational and Therapeutic Center and Ayatollah Kashani Street, Ayatollah Kashani Educational and Therapeutic Center, Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Anoushe Zargar Kharazi
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Hazar Jarib St Isfahan University of Medical Sciences and Health Care Services, Building No. 4, Headquarters, Research and Technology Vice-Chancellor of the University, 1st Floor
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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
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
Esfahan University of Medical Sciences
Full name of responsible person
Seyedehmaryamseyedy
Position
Surgical technologist
Latest degree
Bachelor
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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
Undecided - It is not yet known if there will be a plan to make this available

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

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

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

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