

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 tuina-therapy 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: Tuina-therapy with liquid oil + chamomile plant oil extract Group B: Intervention group two: Tuina-therapy 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 tuina-therapy 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 Sedy

Name of organization / entity

Country

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		Other design features	
Public title Evaluation of the effect of Tuina-therapy with chamomile on the intensity of low back pain in the women operating room		Secondary Ids empty	
Purpose Prevention		Ethics committees	
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:		1	
Age From 25 years old		Ethics committee	
Gender Female		Name of ethics committee Ethical Committee of Isfahan University of Medical Sciences	
Phase 3		Street address Hazar Jarib Street Isfahan University of Medical Sciences	
Groups that have been masked		City Isfahan	
- Participant - Data analyser		Province Isfahan	
Sample size Target sample size: 105		Postal code 7346181746	
Randomization (investigator's opinion) Randomized		Approval date 2022-07-17, 1401/04/26	
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.		Ethics committee reference number IR.ARI.MUI.REC.1401.126	
Blinding (investigator's opinion) Double blinded		Health conditions studied	
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.		1	
Placebo Used		Description of health condition studied Back pain of female staff in the Operating room	
Assignment Parallel		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: Tuina therapy 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr Anoushe Zargar Kharazi

Street address

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

Other areas of specialty/work

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Other areas of specialty/work

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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