Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of abdominal massage with Rosemary oil on the intensity of menstrual pain and bleeding

Protocol summary

Study aim
Determining the effect of abdominal massage with rosemary oil on the severity of menstrual pain and bleeding in nursing and midwifery students of Qom University of Medical Sciences

Design
A controlled, parallel-group, non-blinded, randomized, phase 3 clinical trial on 112 subjects. Block randomization is used for randomization.

Settings and conduct
The present study is an experimental clinical trial study and convenience sampling will be conducted among female nursing and midwifery students of Qom University of Medical Sciences and 112 students will be selected and will be assessed three times during the study period: a baseline assessment at the beginning of the study (before the intervention) and then during the next two menstrual cycles. After the baseline assessment, the students will be randomly assigned to two intervention and control groups. After randomization, the intervention and control groups will receive abdominal massage with rosemary oil and placebo, respectively, during the next two menstrual cycles. In this study, a demographic questionnaire, visual analog scale, and Higam chart will be used.

Participants/Inclusion and exclusion criteria
Inclusion criteria; Age 18 to 25 years؛ Being single؛ Normal menstrual cycles؛ Moderate menstrual pain؛ Menstrual bleeding score less than 100 on the Higam chart

Intervention groups
Thus, in the first 3 days of menstruation, the abdominal area, the upper part of the mons pubis, and the area around the navel are massaged twice a day using the Shiatsu method by the participant himself, in the intervention and control groups, respectively, with 2 cc of 1% rosemary oil with a sunflower oil base and 2 cc of sunflower oil made by Barich Essential Oils Company, in the form of rotating hand movements (without applying pressure), for 15 minutes, while lying down.

Main outcome variables
intensity of menstrual pain and bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250531065989N1**
Registration date: **2025-09-27, 1404/07/05**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-27, 1404/07/05**
Update count: **0**

Registration date
2025-09-27, 1404/07/05

Registrant information

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Mahla Hasanzadeh

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-09-06, 1404/06/15

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of abdominal massage with Rosemary oil on the intensity of menstrual pain and bleeding

Public title

The effect of abdominal massage with Rosemary oil on the intensity of menstrual pain and bleeding

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 25 years Being single The normality of menstrual cycles (the length of menstrual bleeding is 3 to 8 days and the length of the menstrual cycle is 21 to 35 days) moderate menstrual pain (getting a score of 4 to 7 according to the visual analogue scale) Menstrual bleeding score less than 100 according to Higham chart

Exclusion criteria:

Routine use of painkillers in previous menstrual cycles Using drugs such as anticoagulants, oral contraceptives, narcotics and benzodiazepines Chronic diseases (irritable bowel syndrome, inflammatory bowel and chronic pelvic pain) and women's diseases (myoma, fibrocystadenoma, endometriosis, chronic pelvic inflammatory disease, congenital abnormalities of the uterus, ovarian cyst, adenomyosis and metrorrhagia) affecting the results of the study Having skin diseases such as eczema and inflammation in the massage area Presence of abnormal vaginal secretions Existence of stressful factors in the last two months (death of relatives, accident, separation from spouse, etc.) Graduation within the next 6 months Having a history of allergy to rosemary and sunflower

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method in this study is convenience sampling, and participants are divided into two intervention and control groups using block randomization. Block randomization is an important method in clinical trial design that is used to balance the number of participants in different treatment groups, reduce bias, and increase the validity of the results. This method is particularly useful in randomized controlled trials (RCTs) and helps researchers ensure that there are equal numbers of participants in each treatment group. The method is that participants are randomly divided into blocks. Each block contains a number of participants who are assigned to different treatment groups, so that each group has an equal number of participants. In this study, computer algorithms will be used to randomly assign blocks to consider additional parameters and ensure appropriate allocation of participants to groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom university of medical sciences

Street address

Safashahr Ave, Qom

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Province

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3716993456

Approval date

2025-05-05, 1404/02/15

Ethics committee reference number

IR.MUQ.REC.1404.035

Health conditions studied

1

Description of health condition studied

Intensity of menstrual pain and bleeding

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description

Menstrual pain intensity score according to the visual analog scale

Timepoint

Measuring the intensity of menstrual pain before the start of the study as a baseline score and in the next two menstrual cycles in two consecutive months after the intervention.

Method of measurement

10-point Visual Analogue Scale

2

Description
Severity of menstrual bleeding based on Higham chart
Timepoint
Measuring the intensity of menstrual bleeding before the start of the study as a baseline score and in the next two menstrual cycles in two consecutive months after the intervention.
Method of measurement
Higham chart

Secondary outcomes

1

Description
non
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Intervention group: In the intervention group, in the first 3 days of menstruation, the abdomen area, the upper part of the mons pubis, and the area around the navel are massaged twice a day by Shiatsu method by the participant, with 2 cc of 1% rosemary oil based on sunflower oil made by Barich Essence Company, in the form of circular hand movements (without pressure), for 15 minutes, in a lying position.
Category
Treatment - Drugs

2

Description
Control group: In the control group, in the first 3 days of menstruation, 2 times a day, the participant massages the abdominal area, the upper part of the mons pubis, and the area around the navel using Shiatsu method, with 2 cc of sunflower oil manufactured by Barich Essence Company, in the form of circular hand movements (without applying pressure), for 15 minutes, in a lying position.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
Ghoum 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
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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
The use of the entire content of the resulting article is permitted, provided that the source is properly cited.
When the data will become available and for how long
Immediately after the article is published
To whom data/document is available
The use of the materials in this project and article is free for all domestic and foreign researchers, provided the source is cited.
Under which criteria data/document could be used
If the source of the article resulting from this project and the organizational affiliation of the authors of the article are correctly cited, its content may be used in other articles and research projects without hindrance.
From where data/document is obtainable
Vice President for Research and Technology, Qom University of Medical Sciences: Address: Qom - Safashar Street - Jahad Daneshgahi Alley - Shahid Lotfi Niasar (Alley No. 4) - No. 83 Contact Number: 02532852720
What processes are involved for a request to access data/document
Approval by the Council of the Midwifery Department of Qom University of Medical Sciences and later, approval by the Research and Postgraduate Education Council of the Faculty of Nursing and Midwifery, then: approval by the University Research Council and later, approval by the Ethics Committee of Qom University of Medical Sciences.
Comments