

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparative investigation between the effect of aromatherapy with *Rosa damascena* Mill. and Mindfulness-Based Stress Reduction (MBSR) on gestational hypertension in pregnant women

Protocol summary

Study aim

Comparative investigation between the effect of aromatherapy with *Rosa damascena* Mill. and Mindfulness-Based Stress Reduction (MBSR) on gestational hypertension in pregnant women

Design

The clinical trial has two intervention groups and one control group, with parallel, not blinded, simple randomized, on 75 patients, a computer system with sampling software has been used for randomization.

Settings and conduct

The statistical population includes 75 pregnant women who have referred to Yazd health centers to receive routine pregnancy services, and after taking the mother's blood pressure, the diagnosis of pregnancy blood pressure has been considered for them. Then the selected patients are divided into two intervention groups and one control group using simple random method.

Participants/Inclusion and exclusion criteria

Entry conditions: Iranian race, age 18 to 40 years, literacy, singleton pregnancy, systolic blood pressure more than 14 and diastolic blood pressure more than 9, number of pregnancies 4 and less. Conditions for not entering: history of high blood pressure before the current pregnancy or in the first 20 weeks (80/130 or more), suffering from pre-eclampsia and eclampsia in previous pregnancies, taking psychiatric drugs, suffering from anxiety and depression, allergy to rose essential oil or a history of allergies and respiratory diseases

Intervention groups

Intervention group 1: "under aromatherapy treatment" which is treated with 40% *Rosa damascena* essence by inhalation twice a day for 8 weeks. Intervention group 2: "Treated with mindfulness-based stress reduction counseling" in which 8 sessions of 90 minutes twice a week, mindfulness-based stress reduction counseling are

given. Group 3: is the control group that does not receive any intervention.

Main outcome variables

Systolic blood pressure, diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230313057700N1**

Registration date: **2023-05-13, 1402/02/23**

Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**

Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

Name

Mohadese Daneshpajoo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3625 9747

Email address

mmmohadese2016@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative investigation between the effect of aromatherapy with Rosa damascena Mill. and Mindfulness-Based Stress Reduction (MBSR) on gestational hypertension in pregnant women

Public title
Comparative investigation between the effect of aromatherapy with Rosa damascena Mill. and Mindfulness-Based Stress Reduction (MBSR) on gestational hypertension in pregnant women

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Iranian race Age 18 to 40 Being literate Singleton pregnancy The first visit before the 16th week of pregnancy Systolic blood pressure more than 14 and diastolic blood pressure more than 9 The number of pregnancies is 4 or less Healthy sense of smell
Exclusion criteria:
 History of high blood pressure before the current pregnancy or in the first 20 weeks (80/130 or more) Suffering from pre-eclampsia and eclampsia in previous pregnancies Taking psychiatric drugs Suffering from anxiety and depression Allergy to Rosa damascena essential oil or history of allergies and respiratory diseases

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization according to the numbered list by the computer system, they are divided into two intervention groups and one control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

Campus of University of Medical Sciences, first axis of the Haft Bagh Alavi, Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-02-28, 1401/12/09

Ethics committee reference number

IR.KMU.REC.1401.541

Health conditions studied

1

Description of health condition studied

Gestational hypertension

ICD-10 code

O13

ICD-10 code description

Gestational [pregnancy-induced] hypertension without significant proteinuria

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

At the beginning of the intervention - twice a week during the intervention - immediately after the end of the intervention

Method of measurement

Mercury sphygmomanometer model ALPK2 made in Japan

2

Description

Diastolic blood pressure

Timepoint

At the beginning of the intervention - twice a week during the intervention - immediately after the end of the intervention

Method of measurement

Mercury sphygmomanometer model ALPK2 made in Japan

Secondary outcomes

1

Description

Anxiety

Timepoint

Before the start of the intervention - immediately after the end of the intervention

Method of measurement

Questionnaire DASS-21

2

Description

depression

Timepoint

Before the start of the intervention - immediately after the end of the intervention

Method of measurement

Questionnaire 21-DASS

3

Description

Stress

Timepoint

Before the start of the intervention - immediately after the end of the intervention

Method of measurement

Questionnaire 21-DASS

Intervention groups

1

Description

Intervention group: First- the group treated with Rosa damascena aromatherapy - which is treated with 40% Rosa damascena essential oil from Barich Essential Oil Company, inhaled twice a day for 8 weeks.

Category

N/A

2

Description

Intervention group: Second - undergoing treatment with mindfulness-based stress reduction counseling -In 8 sessions of 90 minutes face-to-face and group sessions twice a week, mindfulness-based stress reduction counseling is given.

Category

N/A

3

Description

Control group: It does not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd City Health Center

Full name of responsible person

Seyyed Ali Akbar Mousavi Nadushan

Street address

Kashani Street next to Bahman Hospital

City

Yazd

Province

Yazd

Postal code

8913783343

Phone

+98 35 3624 8021

Fax

+98 35 3628 7198

Email

info@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mr. Dr. Abbas Pardakhti

Street address

Campus of University of Medical Sciences, first axis of the Haft Bagh Alavi, Kerman

City

Kerman

Province

Kerman

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7616913555

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+98 34 3231 0057

Email

mmmohadase2016@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

40

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

Kerman University of Medical Sciences

Full name of responsible person

Masoume Ghazanfarpour

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Campus of University of Medical Sciences, first axis of the Haft Bagh Alavi, Kerman

City

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Province

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Postal code

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Phone

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Email

masoumeh.ghazanfarpour@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Masoume Ghazanfarpour

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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masoumeh.ghazanfarpour@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mohadese Sadat Daneshpajoo

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

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Postal code

7616913555

Phone

+98 34 3231 0057

Email

mmmohadese2016@gmail.com

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the information related to the main outcome is shared

When the data will become available and for how long

Access starts 6 months after results are published

To whom data/document is available

Academic and scientific institutions

Under which criteria data/document could be used

It is allowed to use in order to expand the science of mindfulness. The condition of sending the application is to have a university affiliation.

From where data/document is obtainable

Email to the corresponding author, Masoumeh Ghazanfarpour, Address: Midwifery Research Center, Razi School of Midwifery Nursing, Kerman University of Medical Sciences, Iran. Email: masoumeh.ghazanfarpour@yahoo.com Contact number: 00989136330656

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

The email requesting data to Mrs. Masoumeh Ghazanfarpour, the responsible author, will be answered

after two weeks after going through the administrative process and confirming the identity of the author of the

email.
Comments