Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative investigation between the effectiveness of Mindfulness-Based Stress¬ Reduction (MBSR) and aromatherapy with rosa damascena flower during pregnancy on the distresses caused by breastfeeding and mother-infant attachment style in women referring to Pasargad, fars health centers, 2022

Protocol summary

Study aim

A comparative study of the effect of mindfulness-based stress reduction counseling (MBSR) and aromatherapy with jasmine flowers during pregnancy on breastfeeding distress and mother-infant attachment style

Design

A clinical trial with two intervention groups and one control group, with parallel, blinded, simple randomized groups, on 75 patients, rand function of Excel software was used for randomization.

Settings and conduct

The statistical population includes 75 qualified pregnant women who have referred to health centers in Pasargad city to receive routine pregnancy services and are divided into two intervention groups and one control group using a simple random method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Minimum reading and writing literacy; Iranian nationality; Informed consent to participate in the project; Prime pregnant mothers; 29-33 weeks. Exclusion criteria: Having a history of asthma and allergies; Having an allergy to the rose flower; Having symptoms of mental illness; Mother's addiction to drugs; Having a congenital abnormality based on ultrasounds and screening tests in the first and second trimesters; Taking sedative or anti-anxiety drugs.

Intervention groups

Intervention group 1: is treated with aromatherapy, which is the intervention with 40% rosemary essential oil by inhalation twice a day for 4 weeks. Intervention group 2: is treated with mindfulness-based stress reduction counseling, which is done in 8 sessions of 90 minutes twice a week. Group 3: is the control group that does not receive any intervention.

Main outcome variables

Distress caused by breastfeeding, mother-infant attachment style

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230714058772N1**
Registration date: **2023-07-31, 1402/05/09**
Registration timing: **prospective**

Last update: **2023-07-31, 1402/05/09**
Update count: **0**

Registration date

2023-07-31, 1402/05/09

Registrant information

Name

Masoumeh Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4356 2628

Email address

yashashemi2628@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative investigation between the effectiveness of Mindfulness-Based Stress¬ Reduction (MBSR) and aromatherapy with rosa damascena flower during pregnancy on the distresses caused by breastfeeding and mother-infant attachment style in women referring to Pasargad, fars health centers, 2022

Public title

Comparative investigation between the effectiveness of Mindfulness-Based Stress¬ Reduction (MBSR) and aromatherapy with rosa damascena flower during pregnancy on the distresses caused by breastfeeding and mother-infant attachment style

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Minimum reading and writing literacy Iranian nationality Informed consent to participate in the project Prime pregnant mothers, 29-33 weeks

Exclusion criteria:

Having a history of asthma and allergies Having an allergy to the rose flower Having symptoms of mental illness Mother's addiction to drugs Having a congenital abnormality based on ultrasounds and screening tests in the first and second trimesters Taking sedative or anti-anxiety drugs

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done according to the numbered list by a computer system. Therefore, a number will be assigned to each sample, and after choosing the starting point in the table, read the table numbers from right to left and from top to bottom. It will be low. The first 25 selected numbers in the table will be the control group, the second 25 will be the mindfulness intervention group, and the third 25 will be the aromatherapy intervention 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 Kermam University of Medical Sciences

Street address

Kerman, the beginning of Haft Bagh Alavi axis, University of Medical Sciences campus

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-07-15, 1402/04/24

Ethics committee reference number

IR.KMU.REC.1402.086

Health conditions studied

1

Description of health condition studied

Distress caused by breastfeeding

ICD-10 code

ICD-10 code description

2

Description of health condition studied

mother-infant attachment style

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Distress caused by breastfeeding

Timepoint

before the intervention and immediately after the intervention

Method of measurement

Breastfeeding distress questionnaire

Secondary outcomes

1

Description
Mother-infant attachment
Timepoint
One month after giving birth
Method of measurement
Condon and Corkindle infant attachment questionnaire; Cranley Fetal Attachment Questionnaire

Intervention groups

1

Description
Intervention group: first-The group treated with rosemary aromatherapy, which is treated with 40% rosemary essential oil from Barich Essential Oil Company, by inhalation twice a day for 4 weeks.
Category
N/A

2

Description
Intervention group: 2nd- Undergoing stress reduction counseling based on mindfulness, which is given in 8 face-to-face 90-minute sessions and as a group twice a week.
Category
N/A

3

Description
Control group: does not receive any intervention.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers of Pasargad city
Full name of responsible person
Fatemeh Hosseinpour
Street address
Saadat Shahr, Imam Blvd., facing Imam Jafar Sadiq Hospital
City
Pasargad
Province
Fars
Postal code
7374163196
Phone
+98 71 4356 7777
Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mr. Dr. Abbas Pashti
Street address
Kerman, the beginning of Haft Bagh Alavi axis, University of Medical Sciences campus
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5700
Email
yashashemi2628@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
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

2

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Mr. Dr. Abbas Pashti
Street address
Kerman, the beginning of Haft Bagh Alavi axis, University of Medical Sciences campus
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
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Email
yashashemi2628@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
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Phone
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Email
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Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Masoumeh Hashemi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Kerman, the beginning of Haft Bagh Alavi axis, University of Medical Sciences campus

City
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Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5700

Email
yashashemi2628@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 the announcement of the results

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 conditions for submitting an application are also to have a university affiliation

From where data/document is obtainable

Email to the corresponding author, Masoumeh Ghazanfarpour, address: Midwifery Research Center, Razi Midwifery Nursing School, Kerman University of Medical Sciences, Iran, email: masoumeh.ghazanfarpour@yahoo.com, contact number: 098 34 31325700

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

The data request email to Ms. Masoumeh Ghazanfarpour, the responsible author, will be answered after two weeks after going through the administrative process and verifying the identity of the email author.

Comments