Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparison of the Effectiveness of Mindfulness-based Cognitive Therapy and Quince Fruit Leather Consumption in Nausea and Vomiting During Pregnancy

Protocol summary

Study aim
To determine and compare the effect of mindfulness-based cognitive counseling and fruit lavash consumption on reducing nausea and vomiting of pregnancy in pregnant women referring to obstetrics and gynecology clinics in Bam in 1404

Design
. Random sampling will be conducted from pregnant women referring to obstetrics and gynecology clinics, and the Rhodes questionnaire will be used to measure the severity and frequency of nausea and vomiting before and after the intervention.

Settings and conduct
In this study, pregnant women visiting obstetrics and gynecology clinics in Bam will be divided into three groups: the first group will receive 8 sessions of mindfulness-based cognitive counseling, the second group will consume 5 grams of fruit lavash daily after each main meal, and the third group will receive routine pregnancy care. Data will be collected using the Rhodes questionnaire before and after the intervention and analyzed using statistical software.

Participants/Inclusion and exclusion criteria
First 12 weeks of pregnancy No medical problems such as migraines, thyroid problems, infections and psychiatric disorders Nausea or vomiting for at least three days Age between 18 and 40 years Mild to moderate nausea and vomiting (score 3 to 16 according to the questionnaire)

Intervention groups
The samples will be divided into three groups using a block randomization method: the first group will receive 8 sessions of mindfulness-based cognitive counseling (each session 45 minutes, twice a week). The second group will consume 5 grams of fruit pulp daily after each main meal for 4 weeks. The third group, as the control group, will receive only routine pregnancy care.

Main outcome variables
Reduce nausea and vomiting

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250709066418N1**
Registration date: **2025-07-24, 1404/05/02**
Registration timing: **prospective**

Last update: **2025-07-24, 1404/05/02**
Update count: **0**

Registration date
2025-07-24, 1404/05/02

Registrant information
Name
Fatemeh Ghafari
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
2025-08-16, 1404/05/25
Expected recruitment end date
2026-02-14, 1404/11/25
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the Effectiveness of Mindfulness-based Cognitive Therapy and Quince Fruit Leather Consumption in Nausea and Vomiting During Pregnancy

Public title

comparison of the Effectiveness of Mindfulness-based Cognitive Therapy and Quince Fruit Leather Consumption in Nausea and Vomiting During Pregnancy in Pregnant Women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The first 12 weeks of pregnancy Mild to moderate nausea and vomiting Age between 18 and 40 years old Fetal health according to ultrasound Desire to be pregnant

Exclusion criteria:

medical problems such as migraines, thyroid problems, infections, and psychiatric disorders smell problems tolerance to fruit mental health problems and adverse events in the six months prior to the study severe nausea and vomiting during pregnancy that requires fluid therapy and hospitalization pregnancy complications such as bleeding, threatened miscarriage history of chronic diseases, drug addiction, alcohol and cigarette use, drug allergies, or taking anti-nausea medications (such as vitamin B6 and metoclopramide) at least 48 hours before visiting the clinic. nausea and vomiting due to secondary causes such as peptic ulcer, hepatitis, pyelonephritis, pancreatitis, cholecystitis, appendicitis, gastroenteritis, urinary tract infection, central nervous system disorder, gastroesophageal reflux disease, hyperthyroidism, multiple pregnancy, ectopic pregnancy, molar pregnancy

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a clinical trial with a pre-test and post-test design with a control group. Random sampling will be conducted from pregnant women referring to obstetrics and gynecology clinics, and the Rhodes questionnaire will be used to measure the severity and frequency of nausea and vomiting before and after the intervention. Participants with mild to moderate nausea and vomiting will be included in the study based on the questionnaire and having the inclusion criteria, and will be divided into 3 groups of complementary medicine, counseling, and control using a block randomization method. The complementary medicine group (A), counseling group (B), and control group (C) are randomly generated using R version 4.4.1 software, with 44 blocks of 3 randomly generated.

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

Kerman University of Medical Sciences

Street address

Kerman, Haft Bagh Alavi Square, Kerman University of Medical Sciences Campus

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2025-06-21, 1404/03/31

Ethics committee reference number

IR.KMU.REC.1404.181

Health conditions studied

1

Description of health condition studied

Nausea and vomiting of pregnancy

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea and vomiting of pregnancy: A persistent feeling of nausea and vomiting throughout the day experienced by a pregnant woman and assessed with a standard questionnaire.

Timepoint

Measurement of nausea and vomiting at the beginning of the study and on day 28

Method of measurement
In this study, the standard Rhodes Index of Nausea and Vomiting questionnaire will be used to assess the severity and frequency of nausea and vomiting in pregnant women.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1: Complementary Medicine Group: In this group, individuals consume 5 grams of fruit extract daily after each main meal for 4 weeks, and the questionnaire is completed again after the end of the intervention (4 weeks).
Category
Treatment - Other

2

Description
Intervention Group 2: Counseling Group: In this group, individuals will receive 8 mindfulness-based cognitive counseling sessions (each session 45 minutes) conducted twice a week.
Category
Treatment - Other

3

Description
Control Group 1: The control group in this group receives routine pregnancy care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Gynecological and obstetric clinics in Bam
Full name of responsible person
Fatemeh Ghafari
Street address
Lot 51,Alley 21,Taleghani Street,Bam County,Kerman Province
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr. Hamid Sharifi
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Beginning of Jihad Boulevard, opposite Besat Clinic, Deputy for Research and Technology
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7619813159
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sharifihami@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

Person responsible for general inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Ghafari
Position
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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
This research is titled (Comparison of the effectiveness of mindfulness-based cognitive therapy and the use of lavash in reducing nausea and vomiting during pregnancy). Participation in this research is completely voluntary. Participant information will be kept confidential. The results of the research will be published anonymously.
When the data will become available and for how long
Access period starts 6 months after results are published
To whom data/document is available
Your data will only be available to researchers working in academic and scientific institutions, or people working in industry can apply to receive it.
Under which criteria data/document could be used
Allowed for academic studies
From where data/document is obtainable
Fatemeh Ghaffari fa.ghafari97@gmail.com
What processes are involved for a request to access data/document
It takes about a week.
Comments