Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of mindfulness-based counseling on nausea and vomiting in primery pregnant women

Protocol summary

Study aim
The effect of mindfulness-based counseling on nausea and vomiting in primery pregnant women

Design
A clinical trial with a control group, with parallel groups, without blinding, randomized using the randomized block method.

Settings and conduct
Mindfulness counseling sessions are conducted by a master's student in midwifery counseling who has completed the mindfulness training course in the health centers and clinics of Kuhdasht city after sampling and reaching the quorum.

Participants/Inclusion and exclusion criteria
Entry criteria: primery pregnant , singleton pregnancy, gestational age of 6-10 weeks, not suffering from any underlying disease and threatening abortion symptoms, at least the completion of elementary education, age 18-35, not suffering from any known physical and mental illness, having nausea and Mild or moderate vomiting (scoring 4-12) according to the adjusted quantitative questionnaire for pregnancy nausea and vomiting (PUQE), not using anti-nausea drug treatments Exclusion criteria: unwillingness to continue the intervention, failure to attend two sessions of mindfulness sessions, loss of pregnancy, worsening of nausea and turning into hyperemesis, high-risk pregnancy or occurrence of any kind of complications in pregnancy, use of anti-nausea drugs and vomiting during pregnancy

Intervention groups
Mindfulness based counseling group

Main outcome variables
The score of nausea and vomiting of pregnancy using the adjusted quantitative questionnaire of pregnancy-specific nausea and vomiting (PUQE)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240510061729N1**
Registration date: **2024-05-30, 1403/03/10**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-30, 1403/03/10**
Update count: **0**

Registration date
2024-05-30, 1403/03/10

Registrant information

Name
Maryam Ghobadiasl

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 66 3263 9718

Email address
maryam.ghobadiasl@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-21, 1403/03/01

Expected recruitment end date
2024-09-21, 1403/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of mindfulness-based counseling on nausea and vomiting in primery pregnant women

Public title
Evaluation of the impact of mindfulness-based counseling on the rate of nausea and vomiting during pregnancy"
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Primery pregnant singleton pregnancy Gestational age 6-10 weeks Absence of underlying disease and symptoms threatening abortion Minimum education at the end of elementary school 18_35 years old Not suffering from any known physical and mental illness Not using anti-nausea drug treatments Having mild or moderate nausea and vomiting (scoring 4-12) according to the PUQE questionnaire
Exclusion criteria:
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
First, the participants will be selected by available sampling method, and then they will be placed in the mindfulness-based counseling group and the control group using the random block method of four types.
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 Kermanshah University of Medical Sciences
Street address
No., 68, Shohada Squar
City
Kuhdasht
Province
Lorestan
Postal code
6841771544
Approval date
2023-10-10, 1402/07/18
Ethics committee reference number
IR.KUMS.REC.1402.508

Health conditions studied

1

Description of health condition studied
Nausea and vomiting in primery pregnant women
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Nausea and vomiting score in PUQE questionnaire
Timepoint
Completing the PUQE nausea and vomiting questionnaire immediately and two weeks after the end of the intervention
Method of measurement
Pregnancy Nausea and Vomiting Questionnaire PUQE

Secondary outcomes

1

Description
Pregnancy nausea and vomiting score
Timepoint
Immediately and two weeks after the end of the intervention
Method of measurement
Short 3-question questionnaire on pregnancy nausea and vomiting (PUQE)

Intervention groups

1

Description
Intervention group: in this group, in addition to the usual pregnancy care, counseling based on mindfulness will be done in 8 sessions of 60-90 minutes and twice a week in a group at the relevant health centers.
Category
Other

2

Description
Control group: In this group, people only receive the usual pregnancy care. According to research ethics, at the end, 1-2 sessions on the general principles of mindfulness-based counseling will be provided to the participants of this group as an educational file.

Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Health care centers and clinics in Kuhdasht city
Full name of responsible person
Ghobadiasl Maryam
Street address
No. 68, Shohada Square
City
Kuhdasht
Province
Lorestan
Postal code
6841771544
Phone
+98 918 241 8971 ext. 00986632639718
Email
maryam.ghobadiasl@kums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Cyrus Jalili
Street address
Building No. 2 of Medical Sciences.,Shahid Beheshti Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6714673159
Phone
+98 83 3838 4185
Fax
+98 83 3837 0541
Email
Cjalili@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Ghobadiasl Maryam
Position
Masters Student
Latest degree
Bachelor
Other areas of specialty/work
Reproductive Health
Street address
No. 68, Shohada Square
City
Kuhdasht
Province
Lorestan
Postal code
6841771544
Phone
+98 66 3263 9718
Email
maryam.ghobadiasl@kums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Ghobadiasl Maryam
Position
Masters Student
Latest degree
Bachelor
Other areas of specialty/work
Reproductive Health
Street address
No. 68, Shohada Square
City
Kuhdasht
Province
Lorestan
Postal code
6841771544
Phone
+98 66 3263 9718
Email
maryam.ghobadiasl@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Ghobadiasl Maryam
Position
Masters Student
Latest degree
Bachelor
Other areas of specialty/work
Reproductive Health
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No. 68, Shohada Square
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Lorestan
Postal code
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Phone
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Email
maryam.ghobadiasl@kums.ac.ir

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
Not applicable
Data Dictionary
Not applicable