Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of Educational Intervention based on the Ottawa Nutritional guide on Nausea and Vomiting in Pregnant women

Protocol summary

Study aim
Determining the effect of educational intervention based on the Ottawa nutritional guide on nausea and vomiting in pregnant women Specific goals.

Design
Clinical trial with a control group, a blinded, randomized, on 60 patients. Random Allocation Software was used for randomization.

Settings and conduct
Random placement of pregnant women referring to women's clinics and specialized clinics of selected gynecologists in two groups. Blinding will only be done for the data analyst.

Participants/Inclusion and exclusion criteria
Entry: The gestational age should be 4-16 weeks (4 full weeks to 15 weeks and 7 days)، Singleton pregnancy، Mother's age should be 15-45 years، Be literate in reading and writing، Not suffering from a known physical or mental illness، Do not use drugs to reduce nausea and vomiting except vitamin B6، Score 3-16 in response to the Rhodes questionnaire، Body mass index is equal to or less than 30، Do not have hearing, speech or mental retardation، Do not smoke, use drugs or alcohol. Exit: Obstetrical problems may occur during the study، Vomiting that has a cause other than pregnancy، Being hospitalized due to severe nausea and vomiting of pregnancy.

Intervention groups
The educational program will be presented during two 60-minute sessions in groups of two to five people of the Ottawa nutrition guide training with the methods of lectures, questions and answers, group discussions, lectures and slide shows. The educational content will include: the first session, general Ottawa guidelines for nausea and vomiting and the second session, other points will include lifestyle changes, complementary medicine, acupressure (practical finger acupressure training). During the study, the control group only received routine pregnancy training and did not receive any training from the researcher.

Main outcome variables
Average total score of nausea, vomiting and belching in pregnant women

General information

Reason for update
The expected time for sampling

Acronym

IRCT registration information
IRCT registration number: **IRCT20180218038783N5**
Registration date: **2023-09-03, 1402/06/12**
Registration timing: **prospective**

Last update: **2026-08-26, 1405/06/04**
Update count: **2**

Registration date
2023-09-03, 1402/06/12

Registrant information

Name
Fereshteh Behmanesh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3219 0504

Email address
f.behmanesh@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-01, 1402/08/10

Expected recruitment end date
2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Educational Intervention based on the Ottawa Nutritional guide on Nausea and Vomiting in Pregnant women

Public title

Investigating the Effect of Educational Intervention based on the Ottawa Nutritional guide on Nausea and Vomiting in Pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The gestational age should be 4-16 weeks (4 full weeks to 15 weeks and 7 days). Singleton pregnancy. Mother's age should be 15-45 years. Be literate in reading and writing. Not suffering from a known physical or mental illness. Do not use drugs to reduce nausea and vomiting except vitamin B6. Score 3-16 in response to the Rhodes questionnaire. Body mass index is equal to or less than 30. Do not have hearing, speech or mental retardation. Do not smoke, use drugs or alcohol.

Exclusion criteria:

Obstetrical problems may occur during the study. Vomiting that has a cause other than pregnancy. Being hospitalized due to severe nausea and vomiting of pregnancy.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Pregnant women will be included in the study if they are eligible based on the entry criteria and after obtaining written informed consent. Due to the fact that the subjects of the study do not enter the study at the same time, and the researchers cannot predict in advance which group each person who enters the study will belong to. To assigning the target group to one of the two study groups; The intervention group and the control group (two groups A and B) will use the Block Randomization method with ten blocks. Then the participants will be assigned to one of two groups 1 with a ratio of 1:1 according to the block randomization protocol (produced by Random Allocation Software), so that the researcher cannot predict which group the next person will be in. intervention will be placed. Randomization list based on software output: Allocation concealment In order to hide the random assignment, the codes created by the software will be placed in the envelope so that it is not clear which group the next person will be assigned to. Concealment of random allocation refers to the method used to perform a random sequence on the participants in the study, so that the assigned group is not known before the allocation of the individual. Without hiding the random sequence, there is a possibility of revealing the random sequence, which ultimately weakens the randomization process. Therefore, it is necessary for people who have the criteria to enter the research, a decision to accept or reject participation in the study should be made first and the informed consent form should be completed and then the participants will be assigned to each of the groups. Different methods can be used to hide random allocation. In this study, the method of opaque sealed envelopes with random sequence will be used. Based on the sample size of this research, a number of envelopes are prepared and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, considering that after randomization, the pregnant women themselves and the interventionist cannot be blinded (because the type of intervention is known). Completing questionnaires is also self-reported. Therefore, blinding cannot be done in the first stage. Blinding will only be done for the data analyst.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Health Research Institute

Street address

Ganj Afrooz Street, University Square, Babol University of Medical Sciences

City

Babol

Province
Mazandaran
Postal code
47176-47745
Approval date
2023-08-28, 1402/06/06
Ethics committee reference number
IR.MUBABOL.HRI.REC.1402.079

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
Average total score of nausea, vomiting and belching in pregnant women
Timepoint
During the first two weeks from the beginning of the study, all the participants of the intervention and control groups will be given the Rhodes questionnaire to complete, and the intervention group will also be given a checklist for carrying out the Ottawa recommendations. Then, for another two weeks, the intervention and control groups will be given the Rhodes questionnaire and the intervention group will be given the Ottawa educational guide implementation checklist to complete. Pregnant women should complete the Rhodes questionnaire based on their conditions three days before handing it over to the researcher.
Method of measurement
Rhodes Nausea and Vomiting Index

Secondary outcomes

1

Description
Average sexual satisfaction score
Timepoint
Before the beginning and after the fourth week of the intervention
Method of measurement
Hudson sexual satisfaction questionnaire

Intervention groups

1

Description
Intervention group: After people are placed in two intervention and control groups, two days a week will be determined for pregnant women in the intervention group, one day before the training session, pregnant women will be reminded through a phone call. Educational program during two 60-minute sessions in groups of two to five people, Ottawa nutrition guide training (general guidelines; nutritional recommendations; other recommendations on lifestyle and acupressure) with lecture methods, question and answer and group discussion, lecture with slide show will provide. The educational content will include: the first session, general Ottawa guidelines for nausea and vomiting and the second session, other points will include lifestyle changes, complementary medicine, acupressure (practical finger acupressure training). After the end of the second session, the content will be provided to the intervention group in the form of a booklet for studying at home. During the first two weeks from the start of the study, all the participants of the intervention and control groups will be given the Rhodes questionnaire to complete, and the intervention group will also be given the Ottawa recommendations checklist to complete every night before going to bed. During these two weeks, telephone calls will be made to the intervention group twice a week with an interval of three days to answer their possible questions and to emphasize on doing the things taught. Then, for another two weeks, the intervention and control groups will be given the Rhodes questionnaire and the intervention group will be given the Ottawa educational guide implementation checklist to complete. Pregnant women should complete the Rhodes questionnaire based on their conditions three days before handing it over to the researcher. If someone from the intervention group does not complete the checklist, they will be excluded from the study. After four weeks, both control and intervention groups will complete Hudson's sexual satisfaction questionnaire. Routine pregnancy care will be provided in both groups, and if a member of the intervention and control groups experiences severe nausea and vomiting during pregnancy or is exposed to dehydration and possible complications, they will be referred to medical centers for necessary measures.
Category
Other

2

Description
Control group: During the first two weeks from the beginning of the study, all the participants of the intervention and control groups will be given the Rhodes questionnaire to complete. Then, for another two weeks, the Rhodes questionnaire will be completed again for the intervention and control groups. After four weeks, both control and intervention groups will complete Hudson's sexual satisfaction questionnaire. During the study period, routine pregnancy care will be performed in the control group.
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Women's clinics covered by Babol University of Medical Sciences and selected specialist gynecologist

Full name of responsible person
Dr.Mahdi Rajabnia

Street address
Ganj Afrooz Street, University Square, Babol University of Medical Sciences

City
Babol

Province
Mazandaran

Postal code
47176-47745

Phone
+98 11 3219 9592

Fax
+98 11 3219 0181

Email
ramazan@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Mahdi Rajabnia

Street address
Ganj Afrooz Street, University Square, Babol University of Medical Sciences

City
Babol

Province
Mazandaran

Postal code
47176-47745

Phone
+98 11 3219 9592

Fax
+98 11 3219 0181

Email
ramazan@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Dr.Fereshteh Behmanesh

Position
Assistant Professor of Midwifery and Counseling

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

Street address
Ganj Afrooz Street, University Square, Babol University of Medical Sciences

City
Babol

Province
Mazandaran

Postal code
47745-471676

Phone
+98 11 3219 9592

Fax
+98 11 3219 0181

Email
f.behmanesh@mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr.Fereshteh Behmanesh

Position
Assistant Professor of Midwifery and Counseling

Latest degree
Ph.D.

Other areas of specialty/work
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City
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Province
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Postal code
47745-471676

Phone
+98 11 3219 9592

Fax

+98 11 3219 0181

Email

f.behmanesh@mubabol.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr.fereshteh Behmanesh

Position

Assistant Professor of Midwifery and Counseling

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Ganj Afrooz Street, University Square, Babol University of Medical Sciences

City

Babol

Province

Mazandaran

Postal code

47745-471676

Phone

+98 11 3219 9592

Fax

+98 11 3219 0181

Email

f.behmanesh@mubabol.ac.ir

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

De_identified participant data will be available upon reasonable request from the corresponding author after publication.

When the data will become available and for how long

Immediately after publication for 10 years.

To whom data/document is available

For people working in academic institutions

Under which criteria data/document could be used

Available upon reasonable request. Requestors must submit a scientifically sound proposal, obtain approval from their ethics committee, and sign a Data Access Agreement.

From where data/document is obtainable

The corresponding author (email: f.behmanesh2015@gmial.com) upon reasonable request.

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

Requestors should email the corresponding author with a detailed proposal and evidence of ethical approval. The initial response will be provided within 4 weeks.

Comments