

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of educational intervention based on Ottawa nutritional guidelines on nausea and vomiting and health-related quality of life in women with nausea and vomiting during pregnancy

Protocol summary

Summary

The purpose of this study is to determine the effect of education on nutritional Guideline Ottawa on nausea and vomiting and health-related quality of life in women with nausea and vomiting of pregnancy. The two-group clinical trial was on 60 women pregnancy from 6 to 11 weeks. Daneshamoz and Ahmadi health center were referred in Mashhad. To avoid data transfer between the two groups we use lottery centers for intervention and control groups are determined. Beginning DOS-21 questionnaire, the Rhodes Index will be completed for three days, if the score is 16-3 Rhodes for them, specific quality of life questionnaire completed by interview about the women with nausea and vomiting of pregnancy. Then, Ottawa to guide nutritional will be presented for intervention group at During two sessions Each one 60-minute after Two week of the end we want the intervention and control groups refer to health centers and index Rhodes deliver to scholar. Then, 2 weeks Other. For the intervention group and the control and intervention groups Rhodes index sheets give again. Checklist of Implementation Guide Ottawa Given too. In these two weeks, twice a week, with a distance of three days, we will call for the intervention group. After four weeks of start study, again specific quality of life questionnaire for women with nausea and vomiting of pregnancy Rhodes Index of Nausea and vomiting will be completing for three days at intervention and control groups. than two groups compare.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015011920716N1**

Registration date: **2015-04-23, 1394/02/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-04-23, 1394/02/03

Registrant information

Name

Omid Kiani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3851 5116

Email address

kianibo911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-04-19, 1394/01/30

Expected recruitment end date

2015-08-21, 1394/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational intervention based on Ottawa nutritional guidelines on nausea and vomiting and health-related quality of life in women with nausea and vomiting during pregnancy

Public title

The effect of educational intervention based on Ottawa nutritional guidelines on nausea and vomiting and health-related quality of life in women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1) Signing informed consent and being Iranian and resident of Mashhad. 2) The phone number available for contact. 3) Gestational age 11-6 Week (6 weeks and 1 day to 10 weeks and 6 days) . 4) Singleton pregnancy. 5) Age 18- 35 years old. 6) have a minimum education. 7) No physically and mentally ill. 8) Not using herbal remedies to reduce nausea and vomiting. 9) In response to the tool Rhodes score of 3 to 16 win. 10) BMI is equal to or less than 30. 11) Pregnancy is required. 12) No pregnancy following assisted reproductive techniques. 13) No audio problem and no mental retardation. 14) No history of two consecutive miscarriages before pregnancy. 15) No smoking, no drugs and alcohol. 16) The history of stressful events during the last six months is not. 17) 21-DOS in response to the questionnaire score less than 10, 14, 17, respectively, in the areas of depression, anxiety and stress attend.. Exclusion criteria: 1) No tendency to continue to participate in the study. 2) Obstetric complications occurred during the study. 3) vomit that is a cause other than pregnancy. 4) Admission due to severe nausea and vomiting of pregnancy. 5) Not attending in one of the sessions

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research and Technology,
Mashhad University of Medical Sciences, Next to the
Hoveyzeh cinema, Mashhad

City

Mashhad

Postal code

Approval date

2015-03-14, 1393/12/23

Ethics committee reference number

930441

Health conditions studied

1

Description of health condition studied

Nausea and vomiting during pregnancy

ICD-10 code

O21

ICD-10 code description

Excessive vomiting in pregnancy

Primary outcomes

1

Description

nausea and vomiting pregnancy

Timepoint

Four weeks after the intervention with two-week intervals

Method of measurement

Index of Nausea and vomiting Rhodes

Secondary outcomes

1

Description

Health-related quality of life after 4 weeks of study

Timepoint

The second week until the fourth week intervals for three days

Method of measurement

Health-Related Quality of Life Questionnaire in women with nausea and vomiting of pregnancy

Intervention groups

1

Description

Intervention group: Training Guide Nutrition Ottawa

Category

Prevention

2

Description

Control group: Routin training for obstetric care

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Danesh Amooz health centers

Full name of responsible person

Mahbobeh Soltani

Street address

Farhang Square - Danesh Amooz 10 - Danesh Amooz
Boulevard- Vakil Abad Boulevard

City

Mashhad

2

Recruitment center

Name of recruitment center

Ahmadi health centers

Full name of responsible person

Mahbobeh Soltani

Street address

Abu Taleb intersection- Boulevard Shahid Gharani

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences - Deputy of
Research and Technology

Full name of responsible person

Mohsen Tafaghodi (Pharm.D., Ph.D.) (Deputy of
Research and Technology)

Street address

Vice Chancellor for Research and Technology,
Mashhad University of Medical Sciences, Next to the
Hoveyzeh cinema, MashhadIran

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad University of Medical Sciences - Deputy of
Research and Technology

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahbobeh Soltani

Position

MSc student

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Ibn Sina st., Doctora
cross way, Daneshgah Avenue, Mashhad

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soltanim912@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

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Full name of responsible person

Golmakani Nahid

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Student of Biostatistics

Other areas of specialty/work**Street address**

School of Public Health, 18th daneshgah. Daneshgah
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Mashhad

Postal code**Phone****Fax****Email**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty