Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 determintion 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 to11 weeks Daneshamoz and Ahmadi health center were refer in Mashhad. To avoid data transfer between the two groups we use lottery centers for intervention and control groups are determined. Begining 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
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Iran (Islamic Republic of)
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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 Siences
Full name of responsible person
Mahbobeh Soltani
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MSc student
Other areas of specialty/work
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Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Golmakani Nahid
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http://www.mums.ac.ir/nurse

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Omid Kiani
Position
Student of Biostatistics

Other areas of specialty/work
Street address
School of Public Health, 18th daneshgah. Daneshgah st., Mashhad
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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