

# 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

**City**

Mashhad

**Postal code**

**Phone**

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**Email**

soltanim912@mums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Golmakani Nahid

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

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cross way, Daneshgah Avenue, Mashhad

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golmakanin@mums. ac. ir

**Web page address**

<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

**City**

Mashhad

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

kianibo911@mums.ac.ir

**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*