Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Behavior Therapy on Nausea, Gagging, and Vomiting in Pregnant Women Under 12 Weeks of gestational age: A Clinical Trial

Protocol summary

Summary

The purpose of this study was to investigate the effect of behavior therapy on nausea, gagging and vomiting in pregnancy. 50 pregnant women referred to Imam Khomeini Hospital and Touba Specialized Clinic in the Sari city , at 6-12 weeks of gestational age, moderate and severe nausea and vomiting complaints and single pregnancy were enrolled and non-randomly assigned to the intervention and control groups. Hospitalized mothers, mothers with digestive disorders and thyroid disorders, as well as mothers with high risk pregnancies were not included in the study. Behavioral therapy sessions were conducted for the intervention group in 6 sessions of 50 minutes (for 2 weeks), in which techniques such as self-monitoring, relaxation, stimulant control, and systematic desensitization to mothers were taught. Study was not blinded. The PUEQ questionnaire was filled out by subjects for measuring nausea and vomiting and gagging immediately and 1 month after intervention. Outcome variables: Duration of nausea, vomiting frequency, gagging frequency

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017090322609N2**
Registration date: **2017-11-08, 1396/08/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-08, 1396/08/17

Registrant information

Name

Zohre Shahhosseini

Name of organization / entity

Mazandaran Univercity of Medical Science, Nasibe School Of Nursing and Midwifery

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2017-12-01, 1396/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Behavior Therapy on Nausea, Gagging, and Vomiting in Pregnant Women Under 12 Weeks of gestational age: A Clinical Trial

Public title

Effect of behavioral therapy on nausea and vomiting in pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:Satisfaction to participate in the study; Moderate and severe nausea and vomiting, according to Modified Pregnancy Unique Quantification of Emesis

(PUQE) Score; 6-12 weeks pregnancy; Single pregnancy; Reading and writing literacy. Exclusion criteria:The history of receiving any psychotherapy in the past 6 months; molar pregnancy; Digestive disorders such as gastric ulcer and duodenal ulcer; mothers with high risk pregnancies such as spotting and bleeding; Mothers who are Candidate for Cercelag's; Major psychiatric disorder such as depression and anxiety; hospitalized pregnant women; hearing impairment; receiving other complementary therapies for the treatment of nausea and vomiting (herbal remedies such as ginger, acupressure, acupuncture).

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Not 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
Ethics committee of Mazandaran University of Medical Sciences

Street address
Mazandaran University of Medical Sciences، Beginning of Basij Highway، Juybar Tree Ways، Sari، Mazanran

City
Sari

Postal code

Approval date
2017-07-23, 1396/05/01

Ethics committee reference number
IR.MAZUMS.REC.1396.3173

Health conditions studied

1

Description of health condition studied
Nausea and vomiting in pregnancy

ICD-10 code
O21

ICD-10 code description
Excessive vomiting in pregnancy

Primary outcomes

1

Description
Nausea, Vomiting and Gagging in Pregnancy

Timepoint
Pre-intervention, Immediately and 1 Month after intervention

Method of measurement
Modified Pregnancy Unique Quantification of Emesis (PUQE) Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 6 sessions of behavior therapy for 2 weeks (each session for 50 minutes) are arranged for the intervention group, and techniques such as self-monitoring, relaxation, stimulant control, systematic desensitization to pregnant women are trained.

Category
Behavior

2

Description
Control group: Getting routine pregnancy care, including common medications for the control of nausea and vomiting during pregnancy (if prescribed by a doctor)

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Azam Emamisahebi

Street address
Imam Khomeini Hospital، Amir Mazandarani Avenue، Sari، Mazandaran

City
Sari

2

Recruitment center

Name of recruitment center
Touba Specialized Clinic

Full name of responsible person
Azam Emamisahebi

Street address
Touba Specialized Clinic، Former Medical Faculty، Khazar Boulevard، Sari، Mazandaran

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person
Ravanbakhsh Esmaeili

Street address
Deputy of Research and Technology of Mazandaran University of Medical Sciences، Moalem Square، Moalem Avenue، Sari، Mazandaran

City
Sari

Grant name
-

Grant code / Reference number
-

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

Title of funding source
Vice Chancellor for research of Mazandaran University of Medical Sciences

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
Mazandaran University of Medical Sciences

Full name of responsible person
Azam Emamisahebi

Position
Master

Other areas of specialty/work

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Person responsible for updating data

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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