

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of Benson's relaxation training versus no training on the severity of nausea and vomiting and quality of life in pregnant women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of Benson's relaxation training versus no training on the severity of nausea and vomiting and quality of life in pregnant women

Design

This is a randomized clinical trial, phase II, in which 100 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible pregnant women who will refer to Comprehensive Health Centers in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 30 years, First pregnancy, singleton with the live fetus, Gestational age of 6 to 10 weeks, Nausea and vomiting, Literate Exclusion criteria: High-risk pregnancy, History of infertility, Pyelonephritis, Thyroid disorder, Gastrointestinal disease, Mental disease, Using alcohol, narcotics or cigarette

Intervention groups

Intervention group: Routine pregnancy period plus face-to-face training Benson's relaxation during three consecutive sessions each session 45 to 60 minutes
Control group: Just routine pregnancy period

Main outcome variables

Primary outcome: Nausea and vomiting Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N307**

Registration date: **2019-10-12, 1398/07/20**

Registration timing: **prospective**

Last update: **2019-10-12, 1398/07/20**

Update count: **0**

Registration date

2019-10-12, 1398/07/20

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-01, 1398/08/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Benson's relaxation training versus no training on the severity of nausea and vomiting and quality of life in pregnant women: a randomized clinical trial

Public title

Effect of Benson's relaxation training versus no training

on the severity of nausea and vomiting and quality of life in pregnant women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 30 years, First pregnancy, singleton with live fetus, Gestational age of 6 to 10 weeks, Nausea and vomiting, Literate

Exclusion criteria:

High-risk pregnancy, History of infertility, Pyelonephritis, Thyroid disorder, Gastrointestinal disease, Mental disease, Using alcohol, narcotics or cigarette

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the Comprehensive Health Centers to the intervention and control groups through the drawing of lots. To do this, we will write the names of the Comprehensive Health Centers on the paper sheets. Then, we draw one sheet at a time and assign the Comprehensive Health Centers to the intervention or control group.

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 Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-08-10, 1398/05/19

Ethics committee reference number

IR.UMSHA.REC.1398.424

Health conditions studied

1

Description of health condition studied

Pregnancy nausea and vomiting

ICD-10 code

O21

ICD-10 code description

Excessive vomiting in pregnancy

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

Before the intervention and at the end of fourth week after the intervention

Method of measurement

Using PUQE-24 questionnaire

2

Description

Quality of life

Timepoint

Before the intervention and at the end of fourth week after the intervention

Method of measurement

Using SF-36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine pregnancy period plus face-to-face training Benson's relaxation during three consecutive sessions each session 45 to 60 minutes

Category

Other

2

Description

Control group: Just routine pregnancy period

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Hamadan city

Full name of responsible person

Zahra Jadidi

Street address

School of Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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6517838695

Phone

+98 81 3838 0572

Email

jadidi.zahra77@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Zahra Jadidi

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Soodabeh Aghababaii

Position

Reproductive Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available