Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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
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Person responsible for updating data

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Name of organization / entity
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Dr. Jalal Poorolajal
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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