Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of progressive muscle relaxation on nausea and vomiting in pregnant women

Protocol summary

Study aim
The effect of progressive muscle relaxation on nausea and vomiting in pregnant women

Design
This study is a randomized clinical trial with two groups (intervention and control), pre and post-test design, and not-blinded.

Settings and conduct
Relaxation training is taught to the intervention group during two sessions. In the control group, education is not given by the researcher. The Rhodes questionnaire will complet before and after the intervention by the research units.

Participants/Inclusion and exclusion criteria
Gestational age below 12 weeks based on the first day of the last menstruation or ultrasound; Single pregnancy; Reading and writing literacy; Wanted pregnancy; Ability to use Compact Disc Muscle Relaxation; Lack of major physical and mental illness; Earning a score of less than 10, 14, 17 in response to the DOS-21 questionnaire in depression, anxiety and stress respectively; No use of nausea and vomiting and anti-anxiety drugs; No use of fertility methods for pregnancy; No Smoking, Drug, and Alcohol use; No significant stressful incidents during the past six months; Not using relaxation during pregnancy; Gain a score of 16-3 Rhodes instruments; Unwillingness to participate in the study.

Intervention groups
In the intervention group, Jakobson's progressive muscle relaxation by the researcher is taught in two 60-minute sessions. The intervention group takes relaxation at home for 4 weeks, twice a day (in the morning and evening for 20 minutes. This intervention is not given to control group but only receives routine care from health centers.

Main outcome variables
nausea and vomiting in pregnancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180802040675N1**
Registration date: **2018-08-16, 1397/05/25**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-16, 1397/05/25**
Update count: **0**

Registration date
2018-08-16, 1397/05/25

Registrant information

Name
Zahra SHourgashti

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4335 0519

Email address
shourgashtiz931@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-16, 1397/05/25

Expected recruitment end date
2018-09-21, 1397/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of progressive muscle relaxation on nausea and vomiting in pregnant women

Public title
The effect of Jacobson's progressive muscle relaxation on nausea and vomiting in pregnant women
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
1. Gestational age below 12 weeks based on the first day of the last menstruation or ultrasound 2- Single pregnancy 3- Reading and writing literacy 4- Pregnancy asked 5- Ability to use Compact Disc Muscle Relaxation 6- Lack of major physical and mental illness 7- Earning a score of less than 10, 14, 17 in response to the DOS-21 questionnaire in depression, anxiety and stress, respectively 8- Non-use of nausea and vomiting and anti-anxiety drugs 9- Non-use of fertility methods for pregnancy 10- No Smoking, Drug, and Alcohol 11- Failure to have significant stressful incidents during the past six months 12- Not using relaxation during pregnancy 13- The Rhodes Index score of 16-3
Exclusion criteria:
Unwilling to participate in the study
Age
No age limit
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
The Intended health center is picked out with a draw in such a way that names of five health centers of Mashhad (health center number one, two, three, five, and samen) are written on five papers and is put in a container and a person who is not one of the team members takes a paper out of container which is the name of selected health center. Among the health centers covered by selected center, two health centers are selected randomly based on the most number of referred pregnant women, a center for intervention group and a center for control group .
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraishy Building, University St
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2018-07-28, 1397/05/06
Ethics committee reference number
IR.MUMS.REC.1397.114

Health conditions studied

1

Description of health condition studied
Nausea and vomiting in pregnancy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Nausea and vomiting in pregnant women
Timepoint
Before intervention, two weeks after the intervention, four weeks after the intervention
Method of measurement
"Rhodes" Nausea and Vomiting Standard Test Questionnaire

Secondary outcomes

1

Description
Anxiety, depression and stress in pregnant women
Timepoint
Before the intervention, two weeks after the intervention, four weeks after the intervention
Method of measurement
Depression, Anxiety and Stress Questionnaire DASS-21

Intervention groups

1

Description
Intervention group: CD of progressive muscle relaxation is given to case group. After training, 2 times daily (morning & evening) for one month, case group perform relaxation and then are assessed in next two weeks & 1 month later with using of Rhodes questionnaire and compare with control group.

Category
Lifestyle

2

Description
Control group: CD of progresive mascle relaxation isn't gave to control group. nausea and vomiting is assessed in first visit and in next two weeks & 1 month later with using of Rhodes questionnaire and compared with case group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad No 1 Health Center

Full name of responsible person
Dr Naser Amini

Street address
shahrbani Town, Vakilabad Blvd,Mashhad

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Phone
+98 51 3501 8011

Email
m1hcenter@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraishy Building, University St

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vcresearc@mums.ac.ir

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http://v-research.mums.ac.ir/index.php

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

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
Mashhad University of Medical Sciences

Full name of responsible person
Zahra Shourgashti

Position
Master of Science Student in Public Health

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Mashhad University of Medical Sciences

Full name of responsible person
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Position
Master of Science in Nursing
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Medical Education
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Person responsible for updating data

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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