

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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 complete 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, Ghorashy 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 progressive muscle relaxation isn't given 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

Shahr bani Town, Vakilabad Blvd, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Mashhad University of Medical Sciences, Vice Chancellor for research, Ghorashy Building, University St

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Web page address

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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

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

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Emami moghadam

Position

Master of Science in Nursing

Latest degree

Master

Other areas of specialty/work

Medical Education

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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

Person responsible for updating data**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

Street address