

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of the effect of psycho-education on severity of nausea and vomiting and psychological distress of pregnant women

Protocol summary

Study aim

Determining the effect of psychological training on severity of nausea and vomiting and psychosocial distress in pregnant women referring to comprehensive Zahedan health centers 2018

Design

Two arm parallel group randomized [intervention and control groups(100)]; First on Purpose-based by judgmental sampling, Then, simple allocation will be randomly assigned to either intervention or control groups, 4 weeks outcome assessment.

Settings and conduct

Sampling site: From each of the five areas in Zahedan, 2 clinics will be select with enough space and equipment. In the intervention group, they first receive a pretest and then receive 3 sessions of relaxation based psychological training (progressive muscle relaxation and guided Imagery) within a week individually, and on the basis of designated content. In the control group, they receive pretest and receive routine care. Then the post-test is taken after both 4 weeks of intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Moderate Nausea -History of the nausea and vomiting Pregnancy during at least three days -Beginning nausea and vomiting of pregnancy from 6 to 8 weeks age -Age of at least 18 years Exclusion criteria: -Twin pregnancy or any other conditions with high HCG. - History of underlying diseases in the current pregnancy during past 6 month. -The using of medications e.x Vit B6. - Traumatic and stressful events during 6-month past pregnancy. -Unwanted pregnancy, recurrent abortions, and stillbirth. -Pregnancy consequence infertility. -History of premenstrual syndrome (PMS)

Intervention groups

The intervention group will receive 3 sessions of psycho-education programs based on Relaxation within a week individually, and on the basis of the specified content.

The control group, they received routine care.

Main outcome variables

Psychological distress, severity of nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160924029954N13**

Registration date: **2019-01-18, 1397/10/28**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-18, 1397/10/28**

Update count: **0**

Registration date

2019-01-18, 1397/10/28

Registrant information

Name

Ali navidian

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2482

Email address

alinavidian@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-22, 1397/04/31

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of psycho-education on severity of nausea and vomiting and psychological distress of pregnant women

Public title

Effect of psycho-education in nausea and vomiting pregnancy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

-Moderate Nausea -History of the nausea and vomiting Pregnancy at least during three days -Beginning nausea and vomiting of pregnancy from 6 to 8 weeks -Age of at least 18 years

Exclusion criteria:

Twin pregnancy or any other conditions with high HCG History of underlying diseases in the current pregnancy during past 6 month. The using of medications e.x Vit B6 Traumatic and stressful events during 6-month past pregnancy Unwanted pregnancy, recurrent abortions, and stillbirth Pregnancy consequence infertility History of premenstrual syndrome (PMS)

Age

From **18 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

The sampling participants will be randomize on Purpose-based by judgmental sampling, then will be divided to two groups of intervention(progressive muscle relaxation and guided Imagery) and one control group(routine care) by simple random allocation Individually. Participants will be randomize Using sealed envelopes with a odd (intervention groups) or even (control group) numbers; Also will do allocation concealment.

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 Zahedan University of Medical Sciences

Street address

Dr Hasabaye Square, Persian Gulf Blvd, Zahedan Medical Science Campus Complex

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2018-07-19, 1397/04/28

Ethics committee reference number

IR.ZAUMS.REC.1397.205

Health conditions studied**1****Description of health condition studied**

Nausea and vomiting of pregnancy

ICD-10 code

O21.9

ICD-10 code description

Vomiting of pregnancy, unspecified

2**Description of health condition studied**

Psychological distress

ICD-10 code

F54

ICD-10 code description

Psychological and behavioral factors associated with disorders or diseases classified elsewhere

Primary outcomes**1****Description**

Severity of Nausea and Vomiting

Timepoint

At the beginning of the study, then on the 28th day

Method of measurement

Pregnancy-Unique Quantification of Emesis and Nausea (PUQE) modified questionnaire

2**Description**

Psychological distress

Timepoint

At the beginning of the study, then on the 28th day

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will be receive 3 sessions of relaxation based psychological training) progressive muscle relaxation and guided Imagery) within one week, individually and on the basis of the specified content. Session 1: Introducing, Understanding based on expressing the rules of the group. Session 2: Adjusting the underlying triggers, Session 3: Accepting the Excitement, Also A checklist of Relaxation exercises will be conducted to ensure that women are properly educated. After 4 weeks, the research's questionnaires will be re completed as a post-test by returning home or at the center. The researcher will be maintained relationship by telephone in order to answer potential questions to the participants during these 4 weeks,.

Category

Behavior

2

Description

Control group: This group does not receive any Routine care. After 4 weeks, the research's questionnaires will be re completed as a post-test by returning home or at the center. During these 4 weeks, the researcher will be maintained relationship by telephone in order to answer potential questions to the participants.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Comprehensive Health Center

Full name of responsible person

Ms. Salari

Street address

23th Madjdiye

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Sistan-va-Balouchestan

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9711293658

Phone

+98 54 3349 1163

Email

homeyra.parsi1341@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Hooshang Rafigh Doost

Street address

Doctor Hassabi / College of Zahedan University of Medical Sciences / Deputy of Research and Technology

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Zahedan

Province

Sistan-va-Balouchestan

Postal code

9712234556

Phone

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homeyra.parsi1341@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Ali Navidian

Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

Others

Street address

Mashahir Square, Faculty of Nursing and Midwifery, Zahedan University of Medical Sciences

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98741-96215
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Ali Navidian
Position
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Latest degree
Ph.D.
Other areas of specialty/work
Others
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Person responsible for updating data

Contact

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alinavidian@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Kessler and PUQE questionnaires after unidentifiable individual information

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Used for academic and scientific studies with reference to the reference

From where data/document is obtainable

Homeyra Parsi , homeyra.parsi1341@gmail.com , +98 9155425830

What processes are involved for a request to access data/document

Send the request by email to homeyra.parsi1341@gmail.com , Submit the documentation up to 48 hours after submitting the request

Comments