Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

Kessler psychological distress questionnaire

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
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
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
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9712234556
Phone
+98 54 3329 5792
Email
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
City
Zahedan
Province
Sistan-va-Balouchestan

Postal code
98741-96215
Phone
+98 54 3344 2482
Email
alinavidian@zaums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Ali Navidian
Position
Phd and counseling and guidlince
Latest degree
Ph.D.
Other areas of specialty/work
Others
Street address
Mashahir square, School of Nursing and Midwifery
Zahedan ، Sistani Baloochestan،Iran
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
98561-98189
Phone
+98 54 3344 2482
Fax
Email
alinavidian@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Ali Navidian
Position
Phd and counseling and guidlince
Latest degree
Ph.D.
Other areas of specialty/work
Others
Street address
Mashahir square, School of Nursing and Midwifery
Zahedan ، Sistani Baloochestan،Iran
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
98189-13713
Phone
+98 54 3344 2482
Fax
Email
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