

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of the Effect of Mindfulness-Based Counseling and Training of Effective Communication Skills with the Spouse on Nausea and Vomiting in Pregnant Women

Protocol summary

Study aim

Determining the effect of mindfulness-based counseling and teaching effective communication skills with the spouse on nausea and vomiting in pregnant women

Design

Random clinical trial with control group, with parallel groups, without the possibility of blindness, sample size: 120. The clinical trial includes: one control group and two intervention groups. For randomization, a random table is prepared using On-line software.

Settings and conduct

The study is performed on pregnant clients 8-22 weeks of Amir Al-Momenin Hospital in Semnan. The working method in intervention group (a) ARCT intervention (b) is effective communication training in 4 sessions of 90 minutes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mild and higher nausea according to Rhodes Pregnancy Nausea and Vomiting Questionnaire, gestational age from 8 to 22 weeks of gestation
Exclusion criteria: pregnancy loss, pregnant woman's dissatisfaction with continued cooperation, concomitant physical illness leading to nausea and vomiting, or history of psychiatric disorder

Intervention groups

.(Control group): In this group, routine medical care is performed and virtual education is given to prevent and reduce nausea and vomiting. (Intervention group A): In this group, in addition to the usual medical care, 4 sessions of mind-based counseling are given.
(Intervention group b): In this group, in addition to the usual medical care, 4 sessions of effective communication skills training are given to pregnant mothers in this group.

Main outcome variables

Nausea and vomiting in pregnant women

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201214049706N1**

Registration date: **2021-02-01, 1399/11/13**

Registration timing: **prospective**

Last update: **2021-02-01, 1399/11/13**

Update count: **0**

Registration date

2021-02-01, 1399/11/13

Registrant information

Name

Elaheh Azadbash

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3343 7612

Email address

elaheh.azadbash@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-03, 1400/01/14

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Mindfulness-Based Counseling and Training of Effective Communication Skills with the Spouse on Nausea and Vomiting in Pregnant Women

Public title

Comparison of the Effect of Mindfulness-Based Counseling and Training of Effective Communication Skills with the Spouse on Nausea and Vomiting in Pregnant Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Mild and higher nausea according to the Rhodes Pregnancy Nausea and Vomiting Questionnaire of pregnancy Gestational age from 8 to 22 weeks Single pregnancy The mother has the ability to use a smartphone or Labtab, etc. that can make Internet calls Willingness to participate in the project

Exclusion criteria:

- Loss of pregnancy Dissatisfaction of the pregnant woman to continue cooperation Simultaneous physical illness that leads to nausea and vomiting such as acute pyelonephritis and any gastrointestinal disease leading to nausea and vomiting History of hospitalization due to neurological problems Maternal physical problems that prevent the mother from participating in the 90-minute class

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Random sequence is prepared by the statistical consultant professor and using Online software, a random table for 150 people is provided to the researcher. Given that we have three groups of comparisons, the type of randomization is based on 6 random blocks. The number of blocks is 25 6 blocks that will be prepared using the Sequence table software. The allocation of participants is done using concealment with the method of closed envelopes. In this method, the sequence table designed in the previous section is used. Due to the fact that the type of intervention is known, there is no possibility of blindness.

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 Shahroud University of Medical Sciences

Street address

Unit: 6, floor 4, No. 34, Helal ahmar 7 Ave.,

City

Semnan

Province

Semnan

Postal code

3514815341

Approval date

2020-12-08, 1399/09/18

Ethics committee reference number

IR.SHMU.REC.1399.131

Health conditions studied

1

Description of health condition studied

Nausea and Vomiting in Pregnant Women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Nausea and Vomiting in Pregnant Women

Timepoint

In the fourth intervention session

Method of measurement

Nausea and vomiting questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group (A): In this study, 4 sessions of counseling based on mindfulness are 90 minutes Mindfulness skills training; Session 1: Part 1: Communicating with clients and obtaining information from them; Automatic Thought Identification Introducing Model Self-Regulation: Raisin Exercise; Introduction

Focus on focus with practice in the session. Assignment: Meditation with tape (continued during the experimental period). Part II: Assisting clients in recognizing these thoughts, and teaching the use of thought recording, teaching cognitive distortion to clients. Brief meditation (after each session); Practice mindful eating (cheese and sweet crackers); Conceptual and mental eating; bodyscan. Assignment: Eat 1 snack meal (the rest in the remaining period by increasing the number of grains / snacks) Session 2: Part 1: Diaphragm breathing training and sleep hygiene. Exercise with the wrong adjustment (sweet, high-fat food). Homework: Mini-meditation before meals Scratch 2: Assisting clients in recognizing these thoughts, and teaching the use of thought recording, teaching cognitive distortion to clients. Brief meditation (after each session); Practice mindful eating (cheese and sweet crackers); Conceptual and mental eating; bodyscan. Assignment: Eat 1 snack meal (the rest in the remaining period by increasing the number of grains / snacks) Session 2: Part 1: Diaphragm breathing training and sleep hygiene. Exercise with the wrong adjustment (sweet, high-fat food). Assignment: Mini-meditation before the second meal: training to adjust the mind and label the mind for thoughts, feelings, behaviors. Increase recognition of the personal consequences of chronic anxiety, conduct low-cost analysis of chronic anxiety of clients. Forgiveness meditation. Homework: Eat all meals and snacks carefully Session 3: Part 1: Visual nausea or vomiting; Sitting Yoga Wise Tactics Walking Meditation ÷ Assignment: Participate in Satisfaction and Enjoyment, Enjoy Mineral Foods and Eat / Chopped Foods Part II :: Generating the Hierarchy of Others, Imagination, Facing Acceptance, Exposing Inside Exposure Through Increase Planned Partnership Session 4: Part One: Generating the Hierarchy of Others, Imaginations, Facing Acceptance, Exposing Internal Exposure through Increased Planned Participation Creating a Hierarchy Concerns About Bodybuilding Concerns About Relationships Imagination with Accepting Exposure In vivo by increasing participation Participation in subsequent planning of pregnancy and childbirth Part 2: Review the progress of browsing and techniques in a way that is most useful for review. Other activities Other meetings

Category
Lifestyle

2

Description

Intervention group (B): 4 90-minute sessions of training communication skills training with spouse..Effective communication training: Intervention group (a): In this study, 4 sessions of counseling based on mindfulness are 90 minutes. Session 1: Part 1: Introducing the group and members to each other, familiarity with the working method and structure of the sessions, examining expectations from the program Part II: Increasing Self-Awareness, Emphasizing the Importance of Self-Confidence Session Two: Part One: Identifying Couples 'Beliefs and Expectations about Happiness Part Two: Demonstrating the Impact of Beliefs on Individuals' Feelings and Behavior Session 3: Part One: Listening Skills Training Part Two: Speaking Skills Training Session

Four: Part One: Assessing Conflict Resolution Skills, Training and Practicing Conflict Resolution Skills Part Two: Summarizing and Answering Questions and Performing Post-Test

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital, Semnan

Full name of responsible person

Elaheh Azadbash

Street address

Unit 6, floor 4, No. 34, Helal ahmar 7

City

Semnan

Province

Semnan

Postal code

3514815341

Phone

+98 23 3343 7612

Fax

+98 23 3343 6066

Email

elaheh.azadbash@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Elaheh Azadbash

Street address

Unit 6, Floor 4 ,No.34, Helal Ahmar 7 Ave.

City

Shahroud

Province

Semnan

Postal code

3514815341

Phone

+98 23 3343 7612

Fax

+98 23 3343 6066

Email

elaheh.azadbash@gmail.com

Web page address

Grant name

Dr MohamadHasan Emamian

Grant code / Reference number

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

Yes

Title of funding source

Shahroud University of Medical Sciences
Proportion provided by this source
1
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
Shahroud University of Medical Sciences
Full name of responsible person
Elaheh Azadbash
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Helal Ahmar 7
City
Semnan
Province
Semnan
Postal code
3514815341
Phone
+98 23 3343 7612
Fax
+98 23 3343 6066
Email
elaheh.zadbash@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Elaheh Azadbash
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Helal Ahmar 7
City
Semnan
Province
Semnan
Postal code

3514815341
Phone
+98 23 3343 7612
Fax
+98 23 3343 6066
Email
elaheh.azadbash@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Elaheh Azadbash
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Helal Ahmar 7
City
Semnan
Province
Semnan
Postal code
3514815341
Phone
+98 23 3343 7612
Fax
+98 23 3343 6066
Email
elaheh.azadbash@gmail.com

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
Undecided - It is not yet known if there will be 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
Score of nausea and vomiting in pregnant women before and after mindfulness counseling and effective communication training sessions and the content of mindfulness counseling and effective communication training sessions
When the data will become available and for how long
Since the publication of the article, it is possible to

access valid sites

To whom data/document is available

researchers

Under which criteria data/document could be used

With the consent of all members of the research team,
the data can be transferred

From where data/document is obtainable

Email the free goddess elaheh.azadbash@gmail.com

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

By requesting an email to the goddess Azadbash
elaheh.azadbash@gmail.com

Comments