Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 minutesMindfulness 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 mealsScratch 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 carefullySession 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 childbirthPart 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 BehaviorSession 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

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

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
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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

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Person responsible for updating data

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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