

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The Effect of Consultation Using Positive Approach on Maternal Adaptation and Severity of Pregnancy of Nausea and Vomiting

Protocol summary

Study aim

The Effect of Counseling Using Positive Approach on Maternal Adaptation and Severity of Pregnancy Nausea and Vomiting

Design

The Present Study Is Phase 3 Of A Randomized Clinical Trial, Has A Control Group With Parallel Groups. That Will Be Performed On 60 Patients (30 Interventions And 30 Control Interventions). We Do Not Have Blinding. Eligible Women Will Be Selected By Convenience Sampling Method And Will Be Assigned To Two Intervention And Control Groups Using 4 Random Blocks.

Settings and conduct

The Study Population Includes Women with Nausea and Vomiting That Will be Selected Using the convenience Sampling Method and then Randomly Assigned to the Intervention and Control Groups by the 4 Block Design.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having 3-16 Scores Based on the Reduz Pregnancy Nausea and Vomiting Questionnaire, Gestational Age 6-10 Weeks, Age 18-35 Years, Wanted Pregnancy, Normal Pregnancy and Access to Telephone. Exclusion criteria: Having High-Risk Pregnancy Symptoms, Stressful Events, Unwillingness to Continue Participating in The Study.

Intervention groups

The Intervention Group Six Sessions of Individual Positive Counseling Based on The Silgman Protocol (2006) Will be Done With Emphasizing the three Paths to Happiness (Enjoyment, Commitment, and Meaning in Life). Each Session Will be Done 45 Minutes in 3 Times a Week. The Control Group will Receive Routine Care.

Main outcome variables

Coping and Severity of Nausea and Vomiting in Pregnancy

General information

Reason for update

Changing the start time of sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20150731023423N17**

Registration date: **2020-10-31, 1399/08/10**

Registration timing: **prospective**

Last update: **2020-11-02, 1399/08/12**

Update count: **1**

Registration date

2020-10-31, 1399/08/10

Registrant information

Name

Azam Maleki

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3345 4264

Email address

malekia@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-01, 1399/08/11

Expected recruitment end date

2021-02-23, 1399/12/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Consultation Using Positive Approach on

Maternal Adaptation and Severity of Pregnancy of Nausea and Vomiting

Public title

"The Effect of Consultation Using Positive Approach on Maternal Adaptation and Severity of Pregnancy of Nausea and Vomiting"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having 3-16 Scores Based on RHODES' Pregnancy Nausea and Vomiting Questionnaire Gestational Age 6-10 Weeks Wanted Pregnancy Phone Access Normal Pregnancy The Lack of Chronic Disease The lack of Psychological disease

Exclusion criteria:

Having of High-risk Pregnancy Symptoms Occurrence of Severe Stressful Events Such as Divorce or Death of Loved Ones Not Desire to Continue to Participate in The Study More Than Two Absence in Counseling Sessions

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible Women Will be Selected Using the Convenience Sampling Method. According to the Sample Size, They Will be Randomly Allocated to the Intervention and Control Groups Using Randomized 4-Block by Table of Random Number. The Sequence of Blocks Will be Placed on a Separate Sheet Inside the Matte Envelope. In the Present Study, We do not Have Blinding.

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 Zanjan University of Medical Sciences

Street address

Second building, first floor, Deputy of Research and Technology,,Zanjan University of Medical Sciences, Azadi Blvd, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

۴۵۱۵۶۱۳۱۹۱

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.ZUMS.REC.1398.436

Health conditions studied

1

Description of health condition studied

Pregnancy Nausea and Vomiting

ICD-10 code

O21.0

ICD-10 code description

Mild hyperemesis gravidarum

Primary outcomes

1

Description

Severity of Pregnancy Nausea and Vomiting

Timepoint

Before Intervention, Daily up to two Weeks, Immediately After Intervention, and Four Weeks After Intervention

Method of measurement

RHODES' Nausea and Vomiting Severity Questionnaire

2

Description

Coping With Pregnancy

Timepoint

Before Intervention, Immediately After Intervention, and Four Weeks After Intervention

Method of measurement

Coping With Pregnancy Questionnaire NuPCI

Secondary outcomes

1

Description

Severity of Nausea and Vomiting

Timepoint

Before Intervention, The End of The Intervention and 4 Weeks After The Intervention

Method of measurement

Reduz Nausea and Vomiting questionnaire

2

Description

coping with pregnancy

Timepoint

Before Intervention, and 4 weeks after Intervention

Method of measurement

Hamilton coping with pregnancy

Intervention groups

1

Description

Intervention Group, 6 Sessions Positive Counseling Based on The Protocol of Sligman et al. (2006) will be Received Individually From The 6th Week of Gestation. Each Session will be Done 45 Minutes in Three Times a Week. The Content of The Sessions Includes The Introduction of Three Paths to Happiness (Enjoyment, Commitment, and Meaning in Life) in The Form of a Practice of Forgiveness in Life, a Discussion of Meaning in Life and Its Role in Reducing Negative Emotions, Optimism, Life Satisfaction, Enjoying The Moments and Situations That They Have, Practicing Personal Heritage Skills, Training Subjects to Control Emotions, Acquainting People With Positive Emotions and Its Role in Reducing Pregnancy-related Stressors, Familiarity With One's Abilities and The Role of Support From Other Family Members and Spouse in Adapting to Pregnancy, Reviewing People's Attitudes Towards Commitment and Responsibility in Life and Pregnancy, Practicing The Art of Appreciation in Life, Practicing Thanksgiving in Life, Practicing The Skill of Remembering Three Blessings a Day, Learning to Improve Positive Social Relationships, Constructive Active Response Techniques Will be Discussed. The Control Group Will be Received Only Routine Care, Which Includes Lifestyle Modification to Control Nausea and Vomiting During Pregnancy According to The Protocol of The Ministry of Health,

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Health Centers

Full name of responsible person

Mina Abbasi

Street address

All of Zanjan Health Centers

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45156131910

Phone

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Email

mina.abbac@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

Street address

Second Building, First Floor, Vice Chancellor for Research and Technology, Zanjan University of Medical Sciences, Azadi Blvd. Zanjan, Iran

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Mina Abbasi

Position

Master Student of Counseling In Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Possibility of Dissatisfaction of Participants

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available