

# 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

##### **City**

Zanjan

##### **Province**

Zanjan

##### **Postal code**

45156131910

##### **Phone**

+98 24 1433 8300

#### **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

##### **City**

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##### **Province**

Zanjan

##### **Postal code**

4515613191

##### **Phone**

+98 24 1433 8300

##### **Email**

mina.abbac@yahoo.com

#### **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

##### **Street address**

School of nursing and midwifery ,Zanjan University of Medical Sciences, Gavazang Road, Zanjan, Iran

##### **City**

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**Email**  
mina.abbac@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Azam Maleki  
**Position**  
PhD in Maternal And Child Health  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Midwifery

### Street address

Second Building, First Floor, Social Determinants of Health"Research Center "Vice Chancellor for Research and TechnologyIran, Zanjan University of Medical Sciences,Azadi Blvd, Zanjan,Iran

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### Province

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### Postal code

4515613191

### Phone

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### Email

Malekia@zums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Azam Maleki

### Position

PhD in Maternal And Child Health

### Latest degree

Ph.D.

### Other areas of specialty/work

Midwifery

### Street address

Second Building, First Floor, Social Determinants of Health"Research Center "Vice Chancellor for Research and TechnologyIran, Zanjan University of Medical Sciences, Azadi Blvd, Zanjan,Iran

### City

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### Province

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### Postal code

4515613191

### Phone

+98 24 3342 0651

### Email

Malekia@zums.ac.ir

## 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