# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## The effect of group counseling based on cognitive-behavioral therapy on anxiety and nausea and vomiting in pregnant women

### Protocol summary

**Study aim**
Determining the effect of group counseling based on behavioral cognitive behavioral therapy on anxiety and nausea and vomiting in pregnant women

**Design**
This study was designed as a randomized controlled trial with control

**Settings and conduct**
Group counseling for samples is performed in comprehensive urban health service centers in Tehran. ,

**Participants/Inclusion and exclusion criteria**
Criteria for entering the study: gestational age between 6 to 12 weeks, monogamy مادر مادر Mother's age between 18-18 years  Failure to receive psychological treatment in the last 6 months  Diagnosis of nausea and vomiting and pregnancy anxiety according to the above questionnaires Criteria for leaving the study: . Suffering from mental illness  History of nausea and vomiting before pregnancy  History of gastrointestinal diseases  Complications of pregnancy in the current pregnancy (high-risk pregnancies with symptoms of nausea and vomiting)  Consumption داروهاي Effective on anxiety and nausea and vomiting during pregnancy (such as: androsterone, dimenhydrinate, etc.)

**Intervention groups**
The Ordinary Midwifery Control Group will receive midwifery care in the covered centers, and the intervention group will participate in group counseling classes based on routine midwifery care based on cognitive-behavioral therapy in 6 90-minute counseling sessions for 10 7-person groups per week.

**Main outcome variables**
Pregnancy anxiety, nausea and ejaculation

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20200530047606N1**
Registration date: **2020-06-10, 1399/03/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-10, 1399/03/21**
Update count: **0**

**Registration date**
2020-06-10, 1399/03/21

**Registrant information**

**Name**
Zohre Shafiei

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
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**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-06-09, 1399/03/20

**Expected recruitment end date**
2020-10-11, 1399/07/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of group counseling based on cognitive-behavioral therapy on anxiety and nausea and vomiting in pregnant women

**Public title**

The effect of group counseling based on cognitive-behavioral therapy onanxiety and nausea and vomiting in pregnant women

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

pregnancy age between 6 to 12 weeks (common gestational age) based on the 2019 article by Shoorgashti et al. Single-throat (due to increased nausea and vomiting with increasing number of throats) Maternal age between 40-18 years (due to safer pregnancy) No psychological treatment in the last 6 months Diagnosis of nausea and vomiting and pregnancy anxiety according to the above questionnaires

**Exclusion criteria:**

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **136**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to select the centers where sampling is performed, cluster random sampling method will be used, by selecting centers from different parts of the city that represent the region economically and socially. This means that the city is divided into 5 northwestern, northeastern, southwestern, southeastern and central regions, and a comprehensive health center will be selected from each region. In the next step, the selection of the subjects will be purposeful and based on the entry and exit criteria. In order to identify people who meet the criteria for entering the study and the initial selection of participants, demographic and fertility questionnaires, nausea and vomiting and pregnancy anxiety were presented to all pregnant mothers at 6-12 weeks who came to each center to receive normal pregnancy care. After reviewing the questionnaires, all pregnant mothers with nausea, vomiting, and anxiety were identified at the same time. A total of 136 people are randomly selected using a random number table. Then, in the next step, we will use the random allocation law method to assign 136 pregnant mothers to two control and intervention groups. So that already in each center, forThere are two groups of names, B and A, with 68 people for the intervention group and 68 for the control group. The letters are written on a piece of paper with the number of participants on a piece of paper, and by drawing lots, people select the paper without replacing it, then the created sequence will be recorded. In this way, infected women will be divided into two groups of 68 people (the group receiving the intervention) and the 68-person control group (the group that will receive the usual care during pregnancy).

**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**

Qazvin University of Medical Sciences Ethics Committee

**Street address**

Bahonar Boulevard. Qazvin University of Medical Sciences

**City**

Qazvin

**Province**

Qazvin

**Postal code**

15315-34199

**Approval date**

2020-01-08, 1398/10/18

**Ethics committee reference number**

IR.QUMS.REC.1398.266

## Health conditions studied

### 1

**Description of health condition studied**

Anxiety, nausea and vomiting during pregnancy

**ICD-10 code**

**ICD-10 code description**

Anxiety، nausea ،pregnancy ،vomiting

## Primary outcomes

### 1

**Description**

Pregnancy Anxiety

**Timepoint**

. Pregnancy between 6 and 12 weeks

**Method of measurement**

PRAQ-17

### 2

**Description**

Pregnancy nausea and vomiting

**Timepoint**

6Up to 12 weeks of pregnancy

**Method of measurement**

PUQE

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: In this group, 68 anxious pregnant women who have nausea and ejaculation of pregnancy and routine pregnancy care +6 sessions receive training based on cognitive-behavioral therapy.
**Category**
Behavior

### 2

**Description**
control group: 68 anxious pregnant women who have nausea and vomiting during pregnancy and receive routine pregnancy care.
**Category**
N/A

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
مراکز جامع سلامت شهر تهران
**Full name of responsible person**
Zohreh Shafiei
**Street address**
South Shahran, next to Maaref Cultural Center, No. 55, Unit13
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Qazvin University of Medical Sciences
**Full name of responsible person**
Deputy of research and technology
**Street address**
Shahid Bahonar Blvd. - Qazvin University of Medical Sciences
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info@qums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Qazvin 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**
Qazvin University of Medical Sciences
**Full name of responsible person**
Zohreh Shafiei
**Position**
Senior Midwifery Counseling Student
**Latest degree**
Bachelor
**Other areas of specialty/work**
Midwifery
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## Person responsible for scientific inquiries

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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**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
In the form of an article

**When the data will become available and for how long**
6Months after printing the results

**To whom data/document is available**
Researchers working in academic and scientific institutes and research students in this field.

**Under which criteria data/document could be used**
The use of results in articles and its comparison in new works is unrestricted

**From where data/document is obtainable**
zshafiei49@yahoo.com

**What processes are involved for a request to access data/document**
After the applicant's request via email, the necessary checks will be made and the information will be available shortly after confirmation.

**Comments**