

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of group counseling based on cognitive-behavioral therapy on anxiety and constipation among pregnant women

Protocol summary

Study aim

The effect of group counseling based on cognitive behavioral therapy on anxiety and constipation of pregnant women

Design

A clinical trial with a control group, with parallel groups, has been blinded and randomized

Settings and conduct

Group counseling is provided for samples at Takestan City Health Centers

Participants/Inclusion and exclusion criteria

Gestational age between 10 and 20 weeks Single hook
Mother's age is between 18-35 years old No
psychological treatment in the last 6 months Diagnosis of
constipation and pregnancy anxiety according to the
questionnaire Earn score 119-68 in anxiety (moderate
and severe anxiety) and score of 32-9 in constipation
(moderate and severe constipation) Non arrival: Mental
illness (self-reported) History of irritable bowel syndrome
and constipation before pregnancy (self-reported)
History of digestive diseases History of intestinal surgery
The incidence of pregnancy complications in the current
pregnancy (high risk pregnancy requiring motility and
activity of the mother such as a stable placenta) Having
a history of infertility before pregnancy Use of drugs that
affect anxiety and constipation during pregnancy (such
as laxatives, diuretics, opioid analgesia, antidepressants)

Intervention groups

The control group carries out routine midwifery care in the covered centers and the intervention group, in addition to routine midwifery care, will be offered in group counseling classes based on cognitive-behavioral therapy in 6 consecutive 90-minute counseling sessions for 5 groups of 6 on a weekly basis.

Main outcome variables

anxiety : constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181205041852N1**

Registration date: **2019-02-05, 1397/11/16**

Registration timing: **prospective**

Last update: **2019-02-05, 1397/11/16**

Update count: **0**

Registration date

2019-02-05, 1397/11/16

Registrant information

Name

solmaz ghorbani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 8034

Email address

s.ghorbani@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2019-05-20, 1398/02/30

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 constipation among pregnant women

Public title

The effect of group counseling based on cognitive-behavioral therapy on anxiety and constipation among pregnant women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age from 10 to 20 weeks single hook The age of the mother between the ages of 35 and 18. No psychological treatment in the last 6 months Diagnose constipation and pregnancy anxiety according to the questionnaire Earn score 119-68 in anxiety (moderate and severe anxiety) and score of 32-9 in constipation (moderate and severe constipation)

Exclusion criteria:

Mental illness (self-reported) The history of irritable bowel syndrome and constipation before pregnancy (self-reported) History of digestive diseases history of intestinal surgery Incidence of pregnancy complications in the current pregnancy (high risk pregnancy requiring motility and activity of the mother such as a stable placenta) Have a history of infertility before pregnancy Use of drugs that affect anxiety and constipation in pregnancy (such as laxatives, diuretics, opioid analgesia, antidepressants)

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, the available sampling method was selected by selected health centers, then the samples were selected through simple random sampling or random numbers and divided by random allocation method into two groups of intervention and control.

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 Qazvin University of Medical Sciences

Street address

Bahonar Blvd.-Qazvin University of Medical Sciences

City

qazvin

Province

Qazvin

Postal code

43199-15315

Approval date

2018-12-31, 1397/10/10

Ethics committee reference number

IR.QUMS.REC.1397.267

Health conditions studied**1****Description of health condition studied**

constipation

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes**1****Description**

anxiety

Timepoint

At the beginning of the study, one month and two months after the end of the consultation

Method of measurement

questionnaire

2**Description**

Constipation

Timepoint

At the beginning of the study, one month and two months after the end of the consultation

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group counseling for cognitive-behavioral therapy that takes place in six sessions of 90 minutes.

Category

Treatment - Other

2

Description

Control group: The control group will receive just the usual care of the pregnancy at the comprehensive health centers, and no other work is done for them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin University of Medical Sciences

Full name of responsible person

Solmaz Ghorbani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Peymani

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Solmaz Ghorbani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific

inquiries

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Position

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Other areas of specialty/work

Midwifery

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Other areas of specialty/work

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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

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

Publish as an article

When the data will become available and for how long

Publish as an article

To whom data/document is available

Publish as an article

Under which criteria data/document could be used

Publish as an article

From where data/document is obtainable

Publish as an article

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

Publish as an article

Comments

Publish as an article