

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effects of Cognitive Behavioral counseling on anxiety and worry of pregnant women around the screening of fetal chromosomal abnormality

Protocol summary

Study aim

Determining the effect of Cognitive- Behavioral counseling on the anxiety and worry of pregnant women about screening tests for fetal chromosomal disorders

Design

In this study, 52 pregnant mothers will be included in the study and will be randomly divided into two groups of intervention and control. Demographic questionnaire and Cambridge anxiety and Pregnancy anxiety questionnaire will be provided to both groups with each anxiety and worry score and the average anxiety and worry scores will be calculated by statistical methods.

Settings and conduct

Counseling sessions will be conducted by telephone under the supervision of supervisors and counselors. Questionnaires will be completed before, immediately at the end of the last telephone counseling session and 20-22 weeks of pregnancy in both intervention and control groups.

Participants/Inclusion and exclusion criteria

Having intermediate results in screening in the first trimester of pregnancy; willingness to participate and cooperate in research; have a minimum literacy, gestational age less than 14 weeks; not having any physical illness, pregnant woman does not have known mental illnesses and not taking drugs that affect the psyche; no complications such as miscarriage, moles, bleeding. Conditions for exclusion in the study: unwillingness of participants to continue cooperating in the study; absence for more than two sessions; problems during pregnancy (abortion, moles).

Intervention groups

The members of the intervention group will be 26 people. The intervention is performed in four sessions of 90- 120 minutes in the form of telephone counseling in two sessions per week which will be presented by the researcher. The control group will also receive nutritional counseling during pregnancy within the framework of the intervention group counseling

Main outcome variables

Anxiety and Worry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160608028352N8**

Registration date: **2020-08-29, 1399/06/08**

Registration timing: **prospective**

Last update: **2020-08-29, 1399/06/08**

Update count: **0**

Registration date

2020-08-29, 1399/06/08

Registrant information

Name

Roghieh Kharaghani

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8144

Email address

r.kharaghani@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-05, 1399/06/15

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of Cognitive Behavioral counseling on anxiety and worry of pregnant women around the screening of fetal chromosomal abnormality

Public title
The effects of Cognitive Behavioral counseling on anxiety and worry of pregnant women around the screening of fetal chromosomal abnormality

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Having intermediate results in screening in the first trimester of pregnancy Willingness to participate and collaborate in research Have a minimum literacy Gestational age less than 14 weeks of pregnancy Not having any physical illness Pregnant woman does not have known mental illness and not taking drugs that affect the psyche. No complications such as miscarriage, moles, bleeding, etc.
Exclusion criteria:
 Reluctance to participating in research and absence for more than two sessions Pregnant woman with known mental illnesses and the use of psychotropic drugs that are self-reported. Problems during pregnancy (miscarriage, moles, etc.) that cause double anxiety.

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
Sample selection method among pregnant women will be easy and accessible and then the participants will assigned to two groups of intervention and control using blocked randomization method. Four-dimensional blocks will be created, and in each block, half of the participants will be in the intervention group and the other half will be in the control group, randomly. Selection of the blocks will continue to achieve the total sample size (26 in the intervention group and 26 in the control group). Thirteen blocks will be selected from the random numbers table and the grouping of the participants will conduct according to the conditions set in the previous step.

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

Ethics committee of Zanjan University of Medical Sciences, First floor, North side Azadi square

City

Zanjan

Province

Zanjan

Postal code

4515613113

Approval date

2020-07-14, 1399/04/24

Ethics committee reference number

IR.ZUMS.REC.1399.132

Health conditions studied

1

Description of health condition studied

Worry

ICD-10 code

R45.2

ICD-10 code description

Unhappiness

2

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Worry of pregnant women around the screening of fetal chromosomal abnormality

Timepoint

At baseline, immediately after the intervention and 20-22 week

Method of measurement

Cambridge Worry Questionnaire

2

Description

Anxiety of pregnant women around the screening of fetal chromosomal abnormality

Timepoint

At baseline, immediately after the intervention and 20-22 week

Method of measurement

Pregnancy Related Anxiety Questionnaire (Van den Berg)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The members of the intervention group will be 26 people who will participate in the telephone counseling individually. Cognitive-Behavioral telephone counseling with members of the intervention group will be performed by the researcher, which will be in 4 sessions, two sessions of 90-120 minutes per week based on the prescribed protocol.

Category

Other

2

Description

The control group will consist of 26 people who, in addition to routine pregnancy care, will receive nutritional content with a consultation framework in the intervention group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive urban / rural health service centers of Khorramdareh city

Full name of responsible person

Esmat Vaezi

Street address

Shahid Rajaei St. Health Network

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2

Recruitment center

Name of recruitment center

Comprehensive urban / rural health service centers of Abhar city

Full name of responsible person

Esmat Vaezi

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South Taleghani, Tahmasebi Street Health Network

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3

Recruitment center

Name of recruitment center

Comprehensive urban / rural health service centers of Soltanieh city

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shoghli

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Grant name
Thesis
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
Esmat Vaezi
Position
Msc student of midwifery counselling
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

Contact
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Latest degree
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Other areas of specialty/work
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

A Portion of the data associated with the original outcome is shared

When the data will become available and for how long

Starting the access period from 1400

To whom data/document is available

Information will be available for scholars working in academic and academic institutions

Under which criteria data/document could be used

Apply this type of advice to another target group

From where data/document is obtainable

By e-mail address

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

It will be answered by email and immediately after ensuring the plan is used.

Comments