

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of counseling based on cognitive behavioral therapy on anxiety thoughts of pregnant women with a history of fetal abnormalities

Protocol summary

Study aim

The effect of counseling based on cognitive-behavioral therapy on anxiety thoughts of pregnant women with history of fetal abnormality

Design

A double-blind, randomized clinical trial with intervention and control groups. The method of assigning the intervention to people is randomly and by the method of randomized permutation blocks with a block size of 4 with an assignment ratio of 1 to 1.

Settings and conduct

The intervention in this study starts from the age of 18 to 20 weeks of pregnancy and the end of the intervention is the counseling session after 8 weeks. The place is in health centers. It will be the control and after that the intervention group will receive cognitive-behavioral therapy in the form of 8 sessions once a week

Participants/Inclusion and exclusion criteria

1. Entry requirements of minimum elementary education
2. Age 18 to 40 years 3. Pregnancy age 18 to 20 weeks
4. History of fetal abnormality in previous pregnancy 5. Getting a score one standard deviation higher than the average in the Wells Anxiety Thoughts Questionnaire
Exclusion conditions 1. Suffering from chronic diseases 2. Suffering from mental illnesses during the last year and taking psychoactive drugs 4. Occurrence of pregnancy complications 6. Participation in counseling sessions during the study or three months before the study 7. Facing stressful events such as separation crisis or death of first degree relatives

Intervention groups

The questionnaire will be completed upon entering the study as a pre-test for both the intervention and control groups, and after that the intervention group will receive cognitive-behavioral therapy in the form of 8 sessions once a week.

Main outcome variables

Anxious thoughts

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230726058936N1**

Registration date: **2023-08-29, 1402/06/07**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-29, 1402/06/07**

Update count: **0**

Registration date

2023-08-29, 1402/06/07

Registrant information

Name

Zeinab Davoudi

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-22, 1402/05/31

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling based on cognitive behavioral therapy on anxiety thoughts of pregnant women with a history of fetal abnormalities		groups, and then the intervention group will receive cognitive-behavioral therapy in the form of 8 sessions of 90 minutes, once a week, and the control group will only receive routine prenatal care.	
Public title	The Effect of Cognitive Behavioral Counseling on Anxiety Thoughts in Pregnant Women with a History of Fetal Abnormality	Secondary Ids	empty
Purpose	Education/Guidance	Ethics committees	<u>1</u>
Inclusion/Exclusion criteria	Inclusion criteria: 1. Minimum primary education 2. Age 18 to 40 years 3. Gestational age 18 to 20 weeks 4. History of fetal abnormality in previous pregnancy 5. Score one standard deviation above the mean in Wells anxiety thoughts questionnaire Exclusion criteria: 1. Chronic diseases such as heart disease, high blood pressure, diabetes 2. Mental illness in recent years and taking psychotropic drugs 3. Drug and Cigarette Addiction 4. Pregnancy complications such as preeclampsia, bleeding 5. Absence of more than two sessions in therapy sessions 6. Attending counseling sessions during the study or three months before the study 7. Dealing with stressful events such as separation crisis or death of first-degree relatives	Ethics committee	Name of ethics committee Ethics Committee of Ahvaz Jundishapur University of Medical Sciences Street address Davood Davoodi Alley, Takhti Sq., Emam Ave. City izeh Province Khouzestan Postal code 6391753611
Age	From 18 years old to 40 years old	Approval date	2023-07-23, 1402/05/01
Gender	Female	Ethics committee reference number	IR.AJUMS.REC.1402.253
Phase	N/A	Health conditions studied	<u>1</u>
Groups that have been masked	• Participant • Investigator	Description of health condition studied	anxiety thoughts of pregnant women with a history of fetal abnormalities
Sample size	Target sample size: 46	ICD-10 code	
Randomization (investigator's opinion)	Randomized	ICD-10 code description	
Randomization description	. The method of assigning intervention to the subjects is randomized, using random permutation blocks with block size 4 (using the table related to random permutations) and with a ratio of 1:1. The randomization list is prepared by a statistical expert. Codes assigned to qualified individuals by an outside person who does not know the research objectives will be pIThey will not know who is in the group.	Primary outcomes	<u>1</u>
Blinding (investigator's opinion)	Double blinded	Description	Anxious thoughts score in the Wells Anxiety Thoughts Questionnaire
Blinding description	This way, the researcher and participants will be unaware of who is in what group until the study begins.	Timepoint	Before the intervention began.At the beginning of the study (before the start of the intervention) and at the end of the intervention (8 weeks after the start of the intervention) and one month after the end of the intervention with Wells Anxiety Thought Questionnaire
Placebo	Not used	Method of measurement	Wells Anxiety Thought Questionnaire
Assignment	Other	Secondary outcomes	empty
Other design features	The questionnaire completed at the beginning of the study will be as a pretest of both intervention and control		

Intervention groups

1

Description

Intervention group: The intervention in this study starts from the age of 18 to 20 weeks of pregnancy (that is, after the results of fetal abnormality screening and ultrasound) and the end of the intervention is after 8 weeks of counseling session. The intervention group will receive cognitive-behavioral therapy in the form of 8 sessions of 90 minutes, once a week. Session plan: The first session: introducing the members to each other, the rules and structure of the group, explaining the purpose of the study to the participants, emphasizing Confidentiality of answers, treatment contract, description of how to complete the questionnaire, familiarization with the problem of anxiety thoughts caused by fetal abnormality, description of cognitive-behavioral therapy and the beginning of the second session training: cognitive skills training, review of the topics of the first session, relaxation training, skill training Imagination, presentation of the task of the third session: getting to know the negative thoughts and beliefs that cause negative feelings towards the current pregnancy with regard to the experience of abnormality in the previous pregnancy, reviewing the previous session and checking the completion of the task, describing different types of maladaptive cognitions, recognizing Inconsistent thoughts and self-talks, description of emotions associated with inconsistent cognition, presentation of the assignment of the fourth session: explanation of the effect of psychological factors on the outcome of the current pregnancy, review of the previous session and review of the assignment, training of psychological factors (founding factors, revealing factors, maintaining factors)), presentation of the task of the fifth session: cognitive restructuring, review of the previous session and review of homework, cognitive restructuring and change of negative attitude towards the current pregnancy, presentation of the task of the sixth session: teaching to correct anxious thoughts, review of the previous session and review of homework, review Anxious thoughts and challenging their validity, presentation of the assignment of the seventh session: training to replace positive thoughts instead of anxious thoughts, review of the previous session and review of the assignment of the eighth session: training of communication skills and problem solving, overview, implementation of the post-test

Category

Other

2

Description

Control group: El cuestionario de información demográfica y el cuestionario de pensamientos de ansiedad serán aplicados a gestantes con antecedentes de anomalías fetales con edad gestacional de 18-20 semanas que remitan a centros de salud que reúnan las condiciones para ingresar al estudio, y el grupo control

recibirá únicamente los cuidados habituales del embarazo. Tras finalizar el estudio, el grupo control recibirá el tratamiento basado en el asesoramiento cognitivo-conductual en forma de reunión presencial junto con un CD con el material enseñado al grupo intervención.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Ahvaz University of Medical Sciences

Proportion provided by this source

20

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

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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

No more information

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