Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Sep 2026

The effect of counseling with Beck’s cognitive therapy on anxiety and childbirth fear: a randomized controlled clinical trial

Protocol summary

Study aim
To determine the effect of counseling with Beck cognitive therapy approach on anxiety and fear of delivery

Design
Randomized controlled clinical trial with two parallel arms.

Settings and conduct
This study will be conducted on pregnant women referring to health centers of Ardebil city. The researcher will refer to health centers and will select pregnant women with gestational age of 26 to 28 weeks according to their records, then will call them and they will be invited to participate in the study. In face to face session, the questionnaires of childbirth fear and the Edinburgh Depression Inventory will be completed and the women who obtain a childbirth fear score of over 38 (average and high fear) and the depression score of 12 or less will be included in study and written consent will be obtained. Other questionnaires including socio-demographic information, Spielberger state-trait anxiety inventory will be completed by the researcher. Participants will be randomly assigned into two groups of counseling and control through block randomization. Participants will be asked to contact with the researcher when they go to the hospital and the researcher will complete the questionnaires of anxiety, childbirth fear and childbirth satisfaction with attending in the hospital.

Participants/Inclusion and exclusion criteria
Participants will be nulliparous pregnant women ages 18-35 years old with gestational age 26-28 weeks.

Intervention groups
The intervention group will receive counseling with the Beck cognitive therapy approach and the control group will receive routine pregnancy care.

Main outcome variables
The main outcome variables include fear of childbirth that will be assessed at 36 weeks of pregnancy and the first two hours after delivery by childbirth fear questionnaire and also state and trait anxiety that will be assessed in the active phase of labor by Spielberger State-Trait Anxiety Inventory.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N43**
Registration date: **2018-03-10, 1396/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**
Update count: **0**

Registration date
2018-03-10, 1396/12/19

Registrant information

Name
Mojgan Mirghafourvand

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 1479 6969

Email address
mirghafourvandm@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-07-21, 1397/04/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling with Beck’s cognitive therapy on anxiety and childbirth fear: a randomized controlled clinical trial

Public title

The effect of counseling on anxiety and childbirth fear

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 18 to 35 years old Nulliparous women No history of infertility Fear score more than 38 Having a depression score lower than 12 according to the Edinburgh questionnaire and non-use of psychoactive drugs and antidepressants based on the patient's statement Lack of psychological problems before pregnancy Not having medical problems during pregnancy, including high blood pressure, gestational diabetes, twin and multiple pregnancy and multiple, Placenta and amniotic fluid disorders and ... Having at least secondary education

Exclusion criteria:

Having an indication for cesarean including abnormal fetal presentation, pelvic stenosis, large fetus and ... Change the location to another city until delivery Uncertainty about being able to attend all consultation sessions. Having cardiovascular disease, high blood pressure and liver diseases according to the statement of participant Unwanted pregnancy

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: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be conducted using the website www.random.org and through blocking with block sizes of four and six and an allocation ratio of 1: 1 to the two groups of counseling 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 Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City

Tabriz

Province

East Azarbaijan

Postal code

Iran

Approval date

2017-12-26, 1396/10/05

Ethics committee reference number

IR.TBZMED.REC.1396.837

Health conditions studied

1

Description of health condition studied

Fear and anxiety

ICD-10 code

F40.9

ICD-10 code description

Phobic anxiety disorder, unspecified

Primary outcomes

1

Description

Anxiety

Timepoint

preintervention and active phase of labour

Method of measurement

State – Trait Anxiety Inventory

2

Description

Fear of childbirth

Timepoint

preintervention in 28 week, postintervention in 36 week and 2 hours after childbirth

Method of measurement

Wijma Delivery Expectancy/ Experience Questionnaire Version A and B

Secondary outcomes

1

Description
experience of childbirth
Timepoint
12 to 24 hours after childbirth
Method of measurement
Labor Agentry Scale

2

Description
Childbirth satisfaction
Timepoint
24 hours after childbirth
Method of measurement
Mackey Childbirth Satisfaction Rating Scale

3

Description
Childbirth type
Timepoint
After childbirth
Method of measurement
Medical history

Intervention groups

1

Description
For the intervention group, six 60 to 90 minute group counseling once a week with Beck's cognitive therapy approach will be provided.
Category
Behavior

2

Description
The control group will receive routine cares.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers of Ardabil city
Full name of responsible person
Nasrin Tata
Street address
Hafez Ave. Shahid Shahab Fathi Street,Ardebil
City
Ardebil
Province
Ardabil
Postal code
5615746771
Phone
+98 45 3371 3585
Email
nasrintata66@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Abolghasem Jouyban
Street address
Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3479 6969
Email
mirghafourvandm@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Nasrin Tata
Position
MSc student of conseling in Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing and Midwifery, Southern Shariati St.

City
Tabriz
Province
East Azarbaijan
Postal code
5615746771
Phone
+98 45 3371 3585
Email
nasrintata66@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mojgan Mirghafourvand
Position
PhD of Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Faculty of Nursing and Midwifery, Southern Shariati St.
City
Tabriz
Province
East Azarbaijan
Postal code
ایران
Phone
+98 41 3479 6770
Email
mirghafourvandm@tbzmed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Nasrin Tata
Position
MS.c student of counselling in Midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Faculty of nursing and midwifery, Southern Shariati St.,
City
Tabriz
Province
East Azarbaijan
Postal code
5615746771
Phone
+98 45 3371 3585
Email
nasrintata66@gmail.com

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
Data of participants are privacy.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
The results of clinical study will be published as article.
When the data will become available and for how long
Immediately after publishing the results.
To whom data/document is available
All researchers
Under which criteria data/document could be used
Scientific using with citation to article.
From where data/document is obtainable
Email: mirghafourvandm@tbzmed.ac.ir
What processes are involved for a request to access data/document
Maximum one week after the communication by email.
Comments