

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of counseling with positive approach on anxiety and health functions of women with unplanned pregnancy, a randomized controlled trial study

Protocol summary

Study aim

Determining the effect of counseling with a positive approach on anxiety and health functions, maternal-fetal attachment, depression, and pregnancy anxiety in Renan with unplanned pregnancy and women with an unplanned pregnancy.

Design

A randomized controlled clinical trial with intervention and control groups

Settings and conduct

For the intervention group (27 women), seven individual counseling sessions (60-90 minutes) will be conducted. Meetings will be held once a week for consecutive weeks. The place of consultation will be the consultation room in the nearest health center to the place of residence of the participants. In the present study, the control group (27 women) will receive the usual pregnancy care

Participants/Inclusion and exclusion criteria

Entry criteria include: married women aged 18-49 with unplanned pregnancy, ability to communicate, gestational age 20-24 weeks, scoring less than 140 in the health function questionnaire and 19-8 in the DASS21 questionnaire. Exclusion criteria include: fetal abnormalities, high-risk pregnancy including diabetes, high blood pressure, chronic diseases affecting pregnancy, history or current suffering from mental problems, experience of an unfortunate accident during the last six months.

Intervention groups

The intervention group includes 27 women with unplanned pregnancy who receive 7 individual counseling sessions with a positive approach. The control group is 27 women with unplanned pregnancy who will receive routine pregnancy care

Main outcome variables

general anxiety and health practices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171007036615N10**

Registration date: **2023-01-14, 1401/10/24**

Registration timing: **prospective**

Last update: **2023-01-14, 1401/10/24**

Update count: **0**

Registration date

2023-01-14, 1401/10/24

Registrant information

Name

عصمت مهرابی

Name of organization / entity

دانشگاه علوم پزشکی تبریز

Country

Iran (Islamic Republic of)

Phone

+98 41 3477 0649

Email address

mehrabie@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Parallel
Scientific title The effect of counseling with positive approach on anxiety and health functions of women with unplanned pregnancy, a randomized controlled trial study	Other design features
Public title The effect of counseling with positive approach on anxiety and health functions of women with unplanned pregnancy, a randomized controlled trial study	Secondary Ids empty
Purpose Education/Guidance	Ethics committees
Inclusion/Exclusion criteria Inclusion criteria: Married women aged 18-49 years Women with unplanned pregnancy Gestational age 20 to 24 weeks Verbal and listening ability (ability to communicate) Obtaining a score less than 50% of the average scores obtained by the participants in the questionnaire of health functions Obtaining an anxiety score of 8-19 in the anxiety, stress, depression questionnaire (DASS21) Exclusion criteria: Fetal abnormalities Having a high-risk pregnancy includes diabetes, high blood pressure, chronic diseases that affect pregnancy, such as heart, vascular, lung disease, etc History or current suffering from mental problems or history of hospitalization in a psychiatric hospital Experiencing an unfortunate incident in the last six months, including the death of relatives	1 Ethics committee Name of ethics committee (دانشگاه علوم پزشکی تبریز (کمیته اخلاق در پژوهش) Street address South Shariati Street, Faculty of Nursing and Midwifery, Tabriz City Tabriz Province East Azarbaijan Postal code 5138947977
Age From 18 years old to 49 years old	Approval date 2022-12-04, 1401/09/13
Gender Female	Ethics committee reference number IR.TBZMED.REC.1401.806
Phase N/A	Health conditions studied
Groups that have been masked No information	1 Description of health condition studied general anxiety ICD-10 code ICD-10 code description
Sample size Target sample size: 54	2 Description of health condition studied health practicess ICD-10 code ICD-10 code description
Randomization (investigator's opinion) Randomized	3 Description of health condition studied mother- fetal attachment ICD-10 code ICD-10 code description
Randomization description The participants were allocated to two groups receiving counseling and control through random block classification based on the type of unplanned pregnancy (unwanted or untimely) using RAS software with blocks of 4 and 6 with a ratio of 1:1. The type of allocation will be written on paper and placed in opaque envelopes numbered consecutively (Allocation Concealment). Random allocation will be done by a person not involved in sampling and data collection. The envelopes will be opened by a person not involved in sampling (an expert from the health center) in the order in which people enter the research, and the type of group of people will be determined	4 Description of health condition studied pregnancy anxiety ICD-10 code ICD-10 code description
Blinding (investigator's opinion) Not blinded	5 Description of health condition studied depression ICD-10 code
Blinding description	
Placebo Not used	
Assignment	

ICD-10 code description

Primary outcomes

1

Description

health practices score

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Health Practices Questionnaire-II: HPQ-II

2

Description

general anxiety score

Timepoint

Before the intervention and 4 weeks after the intervention

Method of measurement

Anxiety part of Depression, Anxiety and Stress Scale - 21 Items:DASS21

Secondary outcomes

1

Description

mother- fetal attachment score

Timepoint

Before the intervention and 4 weeks after the end of the intervention

Method of measurement

MFAS: Mother-fetal attachment scale

2

Description

pregnancy anxiety score

Timepoint

Before the intervention and 4 weeks after the end of the intervention

Method of measurement

Revised Pregnancy Related Anxiety Questionnaire: PRAQ-R2)

3

Description

depression

Timepoint

Before the intervention and 4 weeks after the end of the intervention

Method of measurement

the edinburgh postnatal depression scale

Intervention groups

1

Description

Intervention group: The intervention group (27 women) will receive seven individual counseling sessions (60-90 minutes). Meetings will be held once a week for consecutive weeks. The place of consultation will be the nearest health center to the place of residence of the participants

Category

Behavior

2

Description

Control group: The control group (27 women) will receive usual pregnancy care

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

shahid teymouri health center

Full name of responsible person

dr. kolsoom masoumi jarchloo

Street address

behind jahad keshaverzi, amirkabir alley , not far from firooz alley , lale inter section , tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3443 8061

Email

fateme.mirzaloo77784@gmail.com

2

Recruitment center

Name of recruitment center

Marandian Health Center

Full name of responsible person

Dr. Laleh Sadeghi

Street address

Haj Ghaffar Alley, old 17 Shahrivar St., Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3555 3015

Email

fateme.mirzaloo77784@gmail.com

3

Recruitment center

Name of recruitment center

Eram Health Center

Full name of responsible person

Dr. Elham Gholamalipour

Street address

Al-Mahdi Street, District 8, Eram Town, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 2334

Email

fateme.mirzaloo77784@gmail.com

4

Recruitment center

Name of recruitment center

Manzaria Health Center

Full name of responsible person

Dr. Mohammad Reza Mohammad Alizadeh Niaz

Street address

Etesami Alley, Abadani Maskan, Abu Rihan
Crossroads, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 2334

Email

fateme.mirzaloo77784@gmail.com

5

Recruitment center

Name of recruitment center

Shahid Monampour Health Center

Full name of responsible person

Dr Ali Agahi

Street address

Saffron, Saffron Bazaar

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3331 8281

Email

fateme.mirzaloo77784@gmail.com

6

Recruitment center

Name of recruitment center

Ibn Sina Health Center

Full name of responsible person

Dr. Ahmad Namdari

Street address

in front of Imam Hossein Mosque, 18 meters from
Idem, Taleghani town, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6151

Email

fateme.mirzaloo77784@gmail.com

7

Recruitment center

Name of recruitment center

Noor Health Center

Full name of responsible person

Dr. Hamid Mottaghi Khosroshahi

Street address

8th Negarestan St. (Fajr), Noor Town, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3448 5638

Email

fateme.mirzaloo77784@gmail.com

8

Recruitment center

Name of recruitment center

Shahid Yahyawi Health Center

Full name of responsible person

Dr. Mahtab Montazer Babil Aliai

Street address

Azadi St., Shahid Jediri St., Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3334 0444

Email

fateme.mirzaloo77784@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Parviz Shahabi

Street address

Vice Chancellor for Technology Research, Tabriz
University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

fateme.mirzaloo77784@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

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

Dr.Esmat Mehrabi

Position

Ph.D in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

South Shariati Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

b.mehrabi@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Esmat Mehrabi

Position

Ph.D in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Others

Street address

خیابان شریعتی جنوبی

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

b.mehrabi@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Esmat Mehrabi

Position

Ph.D in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

خیابان شریعتی جنوبی

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3479 6770

Email

b.mehrabi@yahoo.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

no

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