

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of logo therapy on anxiety and coping with unplanned pregnancy: a randomized controlled trial

Protocol summary

Study aim

Determining the effect of counseling based logo therapy on anxiety and adaptation to unplanned pregnancy

Design

A controlled, parallel-group, single-blind clinical trial on 52 pregnant women

Settings and conduct

It will be referred to the health centers of Tabriz city, where the details of all women of reproductive age, are available in the web-based system (sib system). The researcher will select the centers from among the centers located in different areas of Tabriz city and the centers with high referrals and will extract the list of all pregnant women 16-24 weeks along with their phone numbers and addresses. In the first stage, centers are selected in a classified manner from different parts of the city with different economic conditions and samples will be selected as available in each center. Then they will be contacted by phone and a brief explanation of the goals and methods of the research will be given. If there is an unplanned pregnancy, people will be requested to be present at the health center at a certain time based on their willingness to participate in the study. In the briefing session, the criteria for entering the study will be reviewed to some extent, and if the women are eligible, the study method will be explained to the participants and the anxiety part of the DASS21 (Depression, Anxiety and Stress Scale - 21 Item) questionnaire will be completed by them.

Participants/Inclusion and exclusion criteria

Married women aged 18-49 years
Women with an unplanned pregnancy with a decision to continue the pregnancy with a gestational age of 16 to 24 weeks
Ability to communicate
Women whose anxiety score is between 8-19 (mild, moderate, severe anxiety) in the DASS-21 questionnaire

Intervention groups

Intervention group: will receive counseling based on logo therapy
Control group: routine prenatal care

Main outcome variables

anxiety and coping

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231107059988N1**

Registration date: **2023-11-25, 1402/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

Fereshteh Baghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3367 0906

Email address

fereshtehbaghaei79@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-05-20, 1403/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of logo therapy on anxiety and coping with unplanned pregnancy: a randomized controlled trial

Public title

The effect of logo therapy on anxiety and coping with unplanned pregnancy: a randomized controlled trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Married women aged 18-49 years Women with an unplanned pregnancy with a decision to continue the pregnancy with a gestational age of 16 to 24 weeks Ability to communicate Women whose anxiety score is between 8-19 (mild, moderate, severe anxiety) in the DASS-21 questionnaire

Exclusion criteria:

Cases of fetal abnormalities Having a high-risk pregnancy including diabetes, high blood pressure, chronic diseases affecting pregnancy such as heart disease, vascular disease, lung disease, etc. History or current suffering from mental problems or history of hospitalization in a psychiatric hospital (according to the individual's own statement) Experiencing an unfortunate incident in the last six months, including the death of a loved one

Age

From **18 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants were randomly classified according to the type of unplanned pregnancy (unwanted or mistimed) using RAS software with blocks of 6 with a ratio of 1:1. Two groups receiving counseling and control will be assigned. 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

Blinding (investigator's opinion)

Single blinded

Blinding description

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.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Tabriz University of Medical Sciences

Street address

College of Nursing and Midwifery-Southern Shariati Street-Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2023-11-06, 1402/08/15

Ethics committee reference number

IR.TBZMED.REC.1402.590

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

Unplanned pregnancy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Anxiety

Timepoint

At the beginning of the study and 4 weeks after the end of the intervention

Method of measurement

DASS-21 questionnaire

2**Description**

Coping

Timepoint

At the beginning of the study and 4 weeks after the end of the intervention

Method of measurement

Revised pregnancy coping inventory: NU-PCI

Secondary outcomes

1

Description

Health practice

Timepoint

At the beginning of the study and 4 weeks after the end of the intervention

Method of measurement

Health Practices Questionnaire-II: HPQ-II

2

Description

Quality of life in pregnancy

Timepoint

At the beginning of the study and 4 weeks after the end of the intervention

Method of measurement

QOL-GRAV: Quality of life-Gravity

Intervention groups

1

Description

Intervention group: the intervention group (26 women), meetings will be held in groups of 3-5 people once a week for consecutive weeks. The place of consultation will be the nearest health center to the place of residence of the participants and duration of sessions are 45-60 minute

Category

Behavior

2

Description

Control group: routine pregnancy care for 26 women in control group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Eram health facility

Full name of responsible person

Dr.Elham Gholamalipour

Street address

Al-Mahdi St,District 8,Aram town

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3232 5148

Email

fereshtehbaghaei79@gmail.com

2

Recruitment center

Name of recruitment center

Babaei health facility

Full name of responsible person

Dr.Alireza Motahhari

Street address

Parvaz-Abbas Duran St., 5 Babaei

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3385 1115

Email

fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center

Sajjadiyeh health facility

Full name of responsible person

Dr.Sadaf Jalilzadeh

Street address

58 / 5,000 Translation results Translation result
Shahid Montazeri street, 20 meter street, next to
Hazrat Abulfazl mosque -

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Phone

+98 41 3544 7281

Email

fereshtehbaghaei79@gmail.com

4

Recruitment center

Name of recruitment center

Qom-tappeh health facility

Full name of responsible person

Dr.Elnaz Afsar

Street address

Qarabaghi St., Serah Beheshti, next to Al-Mahdi
Mosque

City

Tabriz

Province

East Azarbaijan

Postal code
5138947977
Phone
+98 41 3235 7615
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Emamiyyeh health facility
Full name of responsible person
Dr.Mandana Abbaszadeh
Street address
At the end of Imamiya, West Meraj St., next to Sepeh Bank, Shahid Soleimani St.
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3541 9330
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Andisheh health facility
Full name of responsible person
Dr.Mahmood Hajirostamloo
Street address
Andisheh town, Mardani Azar street, next to the emergency department
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3437 3583
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Shahidan Ebrahimi Health facility
Full name of responsible person
Dr.Haniyeh Mahamfar
Street address
University alley, towards Pish qadam Square, not reaching Sari Zami, in front of the CNG station
City
Tabriz
Province
East Azarbaijan

Postal code
5138947977
Phone
+98 41 3544 7281
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Shahid Sabouri Health Facility
Full name of responsible person
Dr.Hossein Yaghchi
Street address
Abbasi Street, Tawanir, towards the highway, in front of the park
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3656 7146
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Cheshm andaz health facility
Full name of responsible person
Dr.Zahra Seydian
Street address
Chahar Rah Abbasi, Haj Hashem station, below Chashmaz Park
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3655 4908
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Seyed Bawafa Health Center
Full name of responsible person
-
Street address
Munjem Blvd.-lower than Alavi Hospital-one shop-facing the gas station
City
Tabriz
Province
East Azarbaijan

Postal code
5138947977
Phone
+98 41 3266 1377
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Akhmaqayeh Health Center
Full name of responsible person
Dr.Mozhan Manouchehri
Street address
Akhmaqayeh - the last station - next to the center of virtue
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3424 1660
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Abuzar Health Center
Full name of responsible person
-
Street address
The end of Sarbaz Shahid street, Sila bazaar to Mulla Zainal, above Abuzar Mosque
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3528 9585
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Jamshid Abad Health Center
Full name of responsible person
Dr.Shahin Khabbazi
Street address
Hojjati St., Fayzieh East Intersection, in front of Shohday Hojjati St
City
Tabriz
Province
East Azarbaijan

Postal code
5138947977
Phone
+98 41 3280 8035
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Hokm abad Health Center
Full name of responsible person
Dr.Dadashi
Street address
Bahar St., in front of Asadabadi Hospital, Kaziyar Alley, below Melli Bank
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3281 4854
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Ostad Jafari Health Center
Full name of responsible person
Dr.Farzad Madadi
Street address
Hojjati St., Moalem Blvd., Akhar Razi St., next to Sabzezar Park
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3286 1666
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Sadeghi Nejad Health Center
Full name of responsible person
Dr.Hakimeh Kabiri
Street address
Hojjati Road, Najjarabad Station, in front of Marandi Alley, next to Khorram Rooz Confectionery
City
Tabriz
Province
East Azarbaijan

Postal code
5138947977
Phone
+98 41 3288 3925
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Sayyad Shirazi Health Facility
Full name of responsible person
Dr.Sonia Ahmadzadeh
Street address
Rezvanshahr, in front of Aghavandi alley
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3235 2121
Email
fereshtehbaghaei79@gmail.com

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Recruitment center

Name of recruitment center
Khatib Health Facility
Full name of responsible person
-
Street address
Khatib, 12 meters Azari, 12 meters Shabnam, in front of the park
City
Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3438 0725
Email
fereshtehbaghaei79@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 President of Technology Research, Tabriz University of Medical Sciences, Tabriz University, Tabriz University
City

Tabriz
Province
East Azarbaijan
Postal code
5138947977
Phone
+98 41 3334 4280
Email
fereshtehbaghaei79@gmail.com
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
Parisa Yavari Kia
Position
Instructure
Latest degree
Master
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parisa Yavari Kia

Position
Instructor
Latest degree
Master
Other areas of specialty/work
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South Shariati Street
City
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Postal code
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Email
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Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parisa Yavari Kia
Position
Instructor
Latest degree
Master
Other areas of specialty/work

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City
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Province
East Azarbaijan
Postal code
5138947977
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Email
p_k_hn@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
There is no further 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