

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effectiveness of cognitive behavioral intervention on perceived stress and quality of life in women with abortion history: a randomized controlled clinical trial

Protocol summary

Study aim

Determining the effect of cognitive behavioral intervention on perceived stress in women with a history of abortion.

Design

Randomized controlled clinical trial

Settings and conduct

This study will be conducted on 62 women 15 to 49 women who have a history of abortion. Women will be selected using convenience sampling method and the perceived stress questionnaire will be completed through the interview by the researcher, and those who score above the cutting point 21.8 will be studied and informed consent will be obtained. Then the individual and social characteristics and the quality of life scales will be completed by researcher through the interview. Participants will be allocated to two groups of intervention and control by using the type of random blocking classified by the type of abortion (spontaneous - induced).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age of 15 to 49 years 2. Losing pregnancy less than 20 weeks of gestational age 3. Minimum education at the level of guidance Exclusion criteria: 1.The history of self-reported mental illness 2. The history of self-reported chronic physical illness 3.Experience of a severe mental crisis over the past three months, such as the death of relatives

Intervention groups

For the intervention group (n=31), cognitive-behavioral group counseling will be conducted at 6 in-person sessions of 60-90 min each, besides two telephone sessions once a week. The controls (n=31) will receive only the routine post abortion care.

Main outcome variables

The main outcome variable is perceived stress.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111219008459N16**

Registration date: **2024-02-11, 1402/11/22**

Registration timing: **prospective**

Last update: **2024-02-11, 1402/11/22**

Update count: **0**

Registration date

2024-02-11, 1402/11/22

Registrant information

Name

Shirin Hasanpoor

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 6770

Email address

hasanpoorsh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-20, 1403/02/01

Expected recruitment end date

2024-10-22, 1403/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Name of ethics committee
The effectiveness of cognitive behavioral intervention on perceived stress and quality of life in women with abortion history: a randomized controlled clinical trial	Ethics committee of Tabriz University of Medical Sciences
Public title	Street address
The effect of counseling on perceived stress and quality of life in women with abortion history	Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue ,Tabriz
Purpose	City
Education/Guidance	Tabriz
Inclusion/Exclusion criteria	Province
Inclusion criteria:	East Azarbaijan
Age between 15 and 49 years Losing pregnancy less than 20 weeks of gestational age at least secondary education	Postal code
Exclusion criteria:	5168743953
The history of self-reported mental illness The history of self-reported chronic physical illness The history of severe self-reported psychological crisis over the past 3 months, such as the death of relatives	Approval date
Age	2024-02-04, 1402/11/15
From 15 years old to 49 years old	Ethics committee reference number
Gender	IR.TBZMED.REC.1402.838
Female	
Phase	Health conditions studied
N/A	<u>1</u>
Groups that have been masked	Description of health condition studied
No information	perceived stress
Sample size	ICD-10 code
Target sample size: 62	ICD-10 code description
Randomization (investigator's opinion)	
Randomized	Primary outcomes
Randomization description	<u>1</u>
Participants will be allocated to two groups of intervention (consulting recipients) and control using the type of random blocking classified by the type of abortion (spontaneous and induced) with the size of the four and six blocks. In order to hide the allocation, the type of intervention on the written paper will be placed in the numbered and opaque envelopes. Envelopes will be opened in order of entry of participants to the study and the type of group of individuals will be determined.	Description
Blinding (investigator's opinion)	perceived stress
Not blinded	Timepoint
Blinding description	Before the intervention and four weeks after the intervention
Placebo	Method of measurement
Not used	Cohen perceived stress questionnaire
Assignment	
Parallel	Secondary outcomes
Other design features	<u>1</u>
Secondary Ids	Description
empty	Quality of life
Ethics committees	Timepoint
<u>1</u>	Before the intervention and four weeks after the intervention
Ethics committee	Method of measurement
	WHO Quality of Life questionnaire
	Intervention groups
	<u>1</u>
	Description
	Intervention group: For the intervention group (n=31), cognitive-behavioral group counseling will be conducted at 6 in-person sessions of 60-90 min each, besides two telephone sessions once a week.
	Category

Other

2

Description

Control group: The controls (n=31) will receive only the routine post abortion care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz health and treatment centers

Full name of responsible person

shirin Hasanpour

Street address

Physical Medicine and Rehabilitation Research Center,
Imam Reza Hospital, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

1475651666

Phone

+98 41 3335 2081

Email

shirinhasanpoor@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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

5168743953

Phone

+98 41 3335 7310

Email

research-vice@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

Shirin Hasanpour

Position

Professsor Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Physical Medicine and Rehabilitation Research Center,
Imam Reza Hospital, Golgasht Street, Tabriz

City

Tabriz

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East Azarbaijan

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Phone

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Email

shirinhasanpoor@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Shirin Hasanpour

Position

Professor Assistant

Latest degree

Ph.D.

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Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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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

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