Clinical Trial Protocol
Iranian Registry of Clinical Trials

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

Public title
The effect of counseling on perceived stress and quality of life in women with abortion history

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 15 and 49 years Losing pregnancy less than 20 weeks of gestational age at least secondary education

Exclusion criteria:
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

Age
From **15 years** old to **49 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
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.

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

City
Tabriz

Province
East Azarbaijan

Postal code
5168743953

Approval date
2024-02-04, 1402/11/15

Ethics committee reference number
IR.TBZMED.REC.1402.838

Health conditions studied

1

Description of health condition studied
perceived stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
perceived stress

Timepoint
Before the intervention and four weeks after the intervention

Method of measurement
Cohen perceived stress questionnaire

Secondary outcomes

1

Description
Quality of life

Timepoint
Before the intervention and four weeks after the intervention

Method of measurement
WHO Quality of Life questionnaire

Intervention groups

1

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
Province
East Azarbaijan
Postal code
1475651666
Phone
+98 41 3335 2081
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.
Other areas of specialty/work
Midwifery
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

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Shirin Hasanpour

Position
Professor 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

Province
East Azarbaijan

Postal code
1475651666

Phone
+98 41 3335 2081

Email
shirinhasanpoor@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