Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of counseling with cognitive-behavioral approach on perceived stress in pregnant women with a history of primary infertility: a randomized controlled clinical trial

Protocol summary

Study aim

To determine the effect of counseling with cognitive-behavioral approach on perceived stress in pregnant women with a history of primary infertility

Design

randomized controlled clinical trial

Settings and conduct

The study will be conducted in AlZahra or Milad Infertility Clinic of Tabriz city on 56 women of 20-40 years old, impregnated using Assisted Reproductive Techniques (ART). The pregnant women who meet the study criteria will be selected using convenience sampling method, and, the perceived stress scale is completed by the researcher through interviewing the participants. Those who are scored 21.8 or more will be included in the study, and the written informed consent will be obtained. Then, the social and demographic characteristics questionnaire, Edinburgh depression during pregnancy scale, the Van den Bergh pregnancy anxiety questionnaire, and, the quality of life scale for pregnancy will be completed by the researcher through interviews. The participants are divided into intervention and control groups using randomized block design according to their age (20 to 30, and 31 to 40 years old), with a block size of 4 and 6.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1-The history of primary infertility Exclusion Criteria : 1. The history of self-reported mental illness 2. The history of self-reported chronic physical illness

Intervention groups

For the intervention group (n=28), 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=28) will receive only the routine pregnancy care.

Main outcome variables

The main outcome variable is perceived stress, which will be measured before the intervention, and 8 weeks after intervention, using the Cohen's Perceived Stress Scale (PSS).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111219008459N12**
Registration date: **2018-11-10, 1397/08/19**
Registration timing: **prospective**

Last update: **2018-11-10, 1397/08/19**
Update count: **0**

Registration date

2018-11-10, 1397/08/19

Registrant information

Name

Shirin Hasanpoor

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-11, 1397/08/20

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of counseling with cognitive-behavioral approach on perceived stress in pregnant women with a history of primary infertility: a randomized controlled clinical trial

Public title
The effect of counseling on perceived stress in pregnant women with a history of primary infertility
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 and 40 years The history of primary infertility at least secondary education Gestational age between the beginning of the 14th week and the end of the 20th week
Exclusion criteria:
Abnormalities in the fetus The history of self-reported mental illness The history of self-reported chronic physical illness (heart disease, hypertension, pulmonary disease, iron deficiency anemia, diabetes, thyroid disease, epilepsy) The history of severe self-reported psychological crisis over the past 3 months, such as the death of relatives
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants are divided into intervention and control groups using randomized block design according to their age (20 to 30, and 31 to 40 years old), with a block size of 4 and 6.In order to hide the allocation, the type of intervention will be written on paper and placed in matt and packed envelopes numbered.The envelopes will be opened in the order of participation of the participants and the type of group 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
2018-10-22, 1397/07/30
Ethics committee reference number
1397-625

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
Kohen perceived stress questionnaire

Secondary outcomes

1

Description
Anxiety
Timepoint
Before the intervention and four weeks after the intervention
Method of measurement
PRAQ: Pregnancy related anxiety questionnaire

2

Description
Depression
Timepoint
Before the intervention and four weeks after the intervention
Method of measurement
Edinburghs Depression during Pregnancy questionnaire

3

Description
Quality of life
Timepoint
Before the intervention and four weeks after the intervention
Method of measurement
QOL-GRAV: Quality of life gravidarum

Intervention groups

1

Description
For the intervention group (n=28), 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
The controls (n=28) will receive only the routine pregnancy care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra or Milad Infertility Clinic
Full name of responsible person
Farideh Golshani
Street address
Baghshomal Crossroad, Southern Artesh Street, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Farideh Golshani
Position
MS.c student of counseling in midwifery
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Instructor

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Reproductive Health

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Person responsible for updating data

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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