

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

AgeFrom **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

Edinburgs 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

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Baghshomal Crossroad, Southern Artesh Street, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Jouyban

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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

Midwifery

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Person responsible for scientific inquiries

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Tabriz University of Medical Sciences

Full name of responsible person

Shirin Hasanpour

Position

Instructor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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Person responsible for updating data

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Latest degree

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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