

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The effect of cognitive-behavioral group counseling on the anxiety of pregnant women with a history of spontaneous abortion

Protocol summary

Study aim

The effect of cognitive-behavioral group counseling on the anxiety of pregnant women with a history of spontaneous abortion

Design

This study is an applied research in the form of randomized trial. The present study will comprise pregnant women referred to health centers in Arak where the previous pregnancy results in abortions and the history of a live child. . The sample size is 64 people. Among 64 who were selected according to the entry criteria and the available conditions, the samples were randomly divided into two groups of 32 control and intervention groups.

Settings and conduct

The population of this study is pregnant women who are referred to health centers in Arak, where the previous pregnancy leads to abortion and the history of a child who is not living. Therefore, considering the criteria for entry and the available conditions, the samples are divided into random blocks of control and intervention. In this study, the effect of cognitive-behavioral group counseling on pregnant women with a history of abortion is conducted for intervention group. . A total of 6 60-minute sessions will be held for the intervention group. Since the standard number of participants in the consultation is 15 people. To access the minimum required sample, the intervention group will be divided into 16 categories and will be given to both groups of counseling. The sessions for the intervention group are 1 session per week and for 6 consecutive weeks. To collect information, a standard questionnaire for determining the level of anxiety Spielberg will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - The age range is 18-40 years - Single-crowned pregnancy with a maximum gestational age of 12 weeks - The company's ability to arrange training classes - Do not take medications related to psychiatric disorders - No history of drug use or smoking - Lack of

infertility history - Anxiety disorder since 3 months ago

Exit criteria: - Unwillingness to continue cooperation - The occurrence of any pregnancy complications during the study (pain, abnormal heartbeat pattern, blood pressure, bleeding, etc.) - Any pregnancy problem that requires medical intervention - Not attending meetings: More than one abstention will be excluded

Intervention groups

The population of this study is pregnant women who are referred to health centers in Arak, where the previous pregnancy leads to abortion and the history of a child who is not living.

Main outcome variables

Level of anxiety before and after intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180123038482N1**

Registration date: **2018-02-09, 1396/11/20**

Registration timing: **prospective**

Last update: **2018-02-09, 1396/11/20**

Update count: **0**

Registration date

2018-02-09, 1396/11/20

Registrant information

Name

Hoda Zaraj

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

h.zaraj@arakmu.ac.ir

Recruitment status

Recruitment complete**Funding source****Expected recruitment start date**

2018-02-20, 1396/12/01

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cognitive-behavioral group counseling on the anxiety of pregnant women with a history of spontaneous abortion

Public title

The effect of group counseling on the anxiety of pregnant women with spontaneous abortion history

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

- The age range is 18-40 years - Single-crowned pregnancy with a maximum gestational age of 12 weeks
- The company's ability to arrange training classes - Do not take medications related to psychiatric disorders - No history of drug use or smoking Lack of infertility history - Anxiety disorder since 3 months ago

Exclusion criteria:

- Unwillingness to continue cooperation - The occurrence of any pregnancy complications during the study (pain, abnormal heartbeat pattern, blood pressure, bleeding, etc.) Any pregnancy problem that requires medical intervention - Not attending meetings: More than one abstention will be excluded

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were randomly divided into two intervention and control groups of 32 groups in each group.

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 Arak University of Medical Sciences

Street address

Vice chancellor Research, Payambar Azam Complex, Basij square, sardasht

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2017-12-17, 1396/09/26

Ethics committee reference number

IR.ARAKMU.REC.1396.222

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

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes**1****Description**

Primary anxiety level

Timepoint

Before intervention - after intervention

Method of measurement

Spielberger questionnaire

Secondary outcomes**1****Description**

Secondary anxiety level

Timepoint

Before intervention - after intervention

Method of measurement

Spielberger questionnaire

Intervention groups

1

Description

Control group: No action

Category

N/A

2

Description

Intervention group: The aim of this study was to investigate the effect of cognitive-behavioral group counseling on pregnant women with a history of abortion in an intervention group. A total of 6 60-minute sessions will be held for the intervention group. How to hold sessions for the intervention group 1 session per week and 6 consecutive weeks.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Health Centers

Full name of responsible person

Hoda Zaraj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr.Mohammad Arjomandzadegan

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Arak University of Medical Sciences, Payambar Azam complex, Basij square, Sardasht

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arjomandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Hoda Zaraj

Position

MSc Student in consultation midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr. Kattayon Vakilian

Position

PhD in reproductive Health and faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

Publishing Article

When the data will become available and for how long

After one year of dissertation defence

To whom data/document is available

All people

Under which criteria data/document could be used

Information

From where data/document is obtainable

Journals

What processes are involved for a request to access data/document

ONline

Comments

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Hoda Zaraj

Position

Msc student in consultation midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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