

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

the effect of self-care education on anxiety and depression in pregnant women with a history of spontaneous abortion referring to health care center in Zahedan 2019

Protocol summary

Study aim

The present study was conducted to investigate the effect of self-care training on anxiety and depression in pregnant women with a history of spontaneous abortion.

Design

This randomized quasi-experimental study was performed on 90 pregnant women with a history of spontaneous abortion who referred to health centers in Zahedan in 2019. The samples were selected by convenience sampling method and randomly assigned to two intervention and control groups. The selected individuals were randomly assigned to intervention and control groups. To this end, some papers were placed in a box with the word "intervention on half of which" and the rest were "control ". Each person picked up a piece of paper from inside the box, and the individuals were randomly assigned to intervention and control groups.

Settings and conduct

Both groups took pre-test groups by completing a personal and fertility information questionnaire, a 6-item Spiel Berger questionnaire, and a short form of Beck Depression Questionnaire. Thereafter, face-to-face training sessions were provided for the intervention group during four 60-minute sessions over two weeks at the Comprehensive Health Centers.

Participants/Inclusion and exclusion criteria

The inclusion criteria entailed: 1) normal and singleton pregnancy, 2) a history of only one spontaneous abortion, 3) pregnancy between 6 and 16 weeks, the exclusion criteria included: absence in training programs for more than one session.

Intervention groups

Face-to-face training sessions were provided for the intervention group during four 60-minute sessions over two weeks at the Comprehensive Health Centers, and a training booklet was delivered to them. On the other hand, the control group only received the usual

pregnancy training in the form of prenatal care.

Main outcome variables

Comparison of anxiety and depression score between two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200509047363N1**

Registration date: **2020-05-16, 1399/02/27**

Registration timing: **retrospective**

Last update: **2020-05-16, 1399/02/27**

Update count: **0**

Registration date

2020-05-16, 1399/02/27

Registrant information

Name

Fateme Hashemzahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 4433 8224

Email address

fatemehashemzahi6350@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-01, 1398/07/09

Expected recruitment end date

2019-12-30, 1398/10/09

Actual recruitment start date

2019-10-01, 1398/07/09
Actual recruitment end date
2019-12-21, 1398/09/30
Trial completion date
2019-12-30, 1398/10/09

Scientific title

the effect of self-care education on anxiety and depression in pregnant women with a history of spontaneous abortion referring to health care center in Zahedan 2019

Public title

the effect of self-care education on anxiety and depression in pregnant women with a history of spontaneous abortion referring to health care center in Zahedan 2019

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

normal and singleton pregnancy a history of only one spontaneous abortion pregnancy between 6 and 16 week lack of known mental disorder; addiction lack of social - psychological crisis; such as the death of loved ones or physical problem and serious illness in the last 6 month Patient Health Questionnaire-9 score of 8-15 (moderate)

Exclusion criteria:

the occurrence of pregnancy problems ; end of pregnancy absence in training programs for more than one session

Age

From **18 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The selected individuals were randomly assigned to intervention and control groups. To this end some papers were placed in a box with the word "intervention on half of which and the rest were "control ". Each person picked up a piece of paper from inside the box; and the individuals were randomly assigned to intervention and control groups.

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

Zahedan University of Medical Sciences

Street address

Doctor Hesabi Squ; Daneshgah Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-09-15, 1398/06/24

Ethics committee reference number

IR.ZAUMS.REC.1398.239

Health conditions studied

1

Description of health condition studied

spontaneous abortion

ICD-10 code

O03

ICD-10 code description

Spontaneous abortion

2

Description of health condition studied

disorder anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

3

Description of health condition studied

depression

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

anxiety

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

2

Description

depression

Timepoint

before intervention and 4 weeks after intervention

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Face-to-face training sessions were provided for the intervention group during four 60-minute sessions over two weeks at the Comprehensive Health Centers, and a training booklet was delivered to them.

Category

Treatment - Other

2

Description

Control group: The control group only received the usual pregnancy training in the form of prenatal care.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Javad Health Center

Full name of responsible person

Mrs Zargari

Street address

Razi Ave.

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2

Recruitment center

Name of recruitment center

Erfan Health Care Center

Full name of responsible person

Mrs Mir

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Recruitment center

Name of recruitment center

Emam Hasan Health Care Center

Full name of responsible person

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Recruitment center

Name of recruitment center

Valiasr Health Care Center

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Nour Mohammad Bakhshani

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Dr Hesabi 'Zahedan University of Medical Sciences

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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
 Zahedan 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
 Zahedan University of Medical Sciences
Full name of responsible person
 Fateme Hashemzahi
Position
 Masters Student
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
 Yes - There is a plan to make this available
Study Protocol
 Yes - There is a plan to make this available
Statistical Analysis Plan
 Yes - There is a plan to make this available
Informed Consent Form
 Yes - There is a plan to make this available
Clinical Study Report
 Yes - There is a plan to make this available
Analytic Code
 Yes - There is a plan to make this available
Data Dictionary
 Yes - There is a plan to make this available
Title and more details about the data/document
 After making people unrecognizable
When the data will become available and for how

long

6 Month after publication of the article

To whom data/document is available

university researchers

Under which criteria data/document could be used

For use in academic and scientific studies and research

From where data/document is obtainable

Fateme Hashemzahi fatemehashemzahi6350@gmail.com

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

Send a request to fatemehashemzahi6350@gmail.com
and reply within 48 hour

Comments