

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Design, implementation and evaluation of a psychosocial intervention in women with recurrent miscarriage: a multi-method mixed study

Protocol summary

Study aim

General Objective Design, implementation and evaluation of a psycho-social intervention in women with recurrent miscarriage: a multi-method mixed study psychological-social experiences of women with frequent abortions (preparation of the intervention plan) Implementation and evaluation of psycho-social intervention

Design

the first qualitative phase, the second phase of intervention design, The third phase of implementing the intervention on 92 women- a clinical trial with a control group - one blinded - randomized

Settings and conduct

medical centers of Ahvaz University of Medical Sciences (Sina, Razi, Imam Khomeini). Psychosocial support for women is explained with a qualitative approach. The intervention is designed based on the results of the qualitative phase and review of studies, and the intervention is tested. Allocation will be 1:1 in blocks of 4 and 6. Matte sealed envelopes that are numbered and type of intervention is written inside them. These envelopes will be prepared by a non-involved researcher.

Participants/Inclusion and exclusion criteria

Inclusion criteria The ability to speak Farsi; the absence of any physical and mental illness; a score above 12 in the depression questionnaire; a score above 30 in the anxiety questionnaire; no smoking; frequent spontaneous abortions in a row of two (or more); a healthy and singleton fetus. 20 to 45 years old; childless or having any number of children before lost pregnancies; last abortion in the last 1 to 6 months. Non-entry criteria occurrence of stressful events such as death of relatives, divorce, etc.; pregnancy; Severe depression and anxiety.

Intervention groups

The intervention group is presented with prepared content. The control group received routine supportive care.

Main outcome variables

psycho-social support perceived, the level of anxiety, the level of depression, the level of perceived stress, the quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231008059654N1**

Registration date: **2023-11-01, 1402/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-01, 1402/08/10**

Update count: **0**

Registration date

2023-11-01, 1402/08/10

Registrant information

Name

afsaneh talebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3340 1207

Email address

afsanehtalebi68@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-06-20, 1403/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Design, implementation and evaluation of a psychosocial intervention in women with recurrent miscarriage: a multi-method mixed study

Public title

Design, implementation and evaluation of a psychosocial intervention in women with recurrent miscarriage: a multi-method mixed study

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Ability to understand and speak Persian
Absence of any physical and mental illness
Obtaining a score above 12 based on the Edinburgh Depression Questionnaire
Getting a score above 30 based on the Spielberger Anxiety Questionnaire
No smoking
Recurrent spontaneous abortion as two or three (or more) consecutive abortions
The fetus is healthy and single
Age 20-45 years
Childless or having any number of children before the missed pregnancies
Last abortion within the last 1 to 6 months
Willingness to participate in research
The ability to provide rich and sufficient information on the subject being studied

Exclusion criteria:

occurrence of stressful events such as death of relatives, divorce, etc.
pregnancy
Severe depression and anxiety

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Women with frequent miscarriages who are hospitalized in hospitals in Ahvaz will be randomly divided into intervention and control groups. Sampling will be done easily. After the initial selection of the samples, the allocation in the intervention and control groups will be random with a ratio of 1:1 in blocks of 4 and 6. In order to hide the allocation, opaque sealed envelopes that are numbered in order and the type of intervention is written inside them will be used. These envelopes will be prepared by the researcher not involved in data collection. The envelopes will be opened after completing the pre- test and at the same moment of assigning people to the groups, and the first envelope will be given to the first person who meets the study entry criteria and

will continue until the desired sample size is completed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analysis of the data and the evaluation of the results are done using SPSS software by the professor of statistics and without the knowledge of the intervention and control groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

research ethics committees of Ahvaz Jundishapur University of Medical Sciences

Street address

5th floor, Baharan Building, 21 Golestan St., third dead end, Golestan Square, Azimieh, Alborz

City

Ahvaz

Province

Khouzestan

Postal code

3155768877

Approval date

2023-10-07, 1402/07/15

Ethics committee reference number

IR.AJUMS.REC.1402.347

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

psychosocial intervention in women with recurrent miscarriage

ICD-10 code

N96

ICD-10 code description

Recurrent pregnancy loss

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

Perceived psycho-social support score

Timepoint

before the start of the intervention and 4 weeks after the start of the intervention

Method of measurement

Secondary outcomes

1

Description

anxiety score

Timepoint

before the start of the intervention and 4 weeks after the start of the intervention

Method of measurement

Spielberger anxiety questionnaire

2

Description

depression score

Timepoint

before the start of the intervention and 4 weeks after the start of the intervention

Method of measurement

Edinburgh depression questionnaire

3

Description

stress score

Timepoint

before the start of the intervention and 4 weeks after the start of the intervention

Method of measurement

perceived stress questionnaire

4

Description

quality of life score

Timepoint

before the start of the intervention and 4 weeks after the start of the intervention

Method of measurement

36-question quality of life questionnaire

Intervention groups

1

Description

Intervention group: In the intervention group, content has been prepared for women with frequent abortion experience, which will probably include the implementation of a training program for midwives and.... during the hospitalization of women in the hospital (psycho-social support measures) and after discharge when visiting the centers Health care will be provided through a trained health team.

Category

Other

2

Description

Control group: In the control group, only routine supportive care will be provided by health team members working in health centers.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital, Sina hospital, Razi hospital

Full name of responsible person

Afsaneh talebi

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Esfand North Alley, Farvardin St., Ahvaz, Khuzestan Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Assistance of Research and Technology of Ahvaz Jundishapur University of Medical Sciences

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Esfand North, Farvardin, Ahvaz, Khuzestan province

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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

Ahvaz 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

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Person responsible for general inquiries

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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