Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

psychosocial support questionnaire

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
Street address
Esfand North Alley, Farvardin St., Ahvaz, Khuzestan Province
City
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6135715794
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+98 61 3311 0000
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aduaum@ajums.ac.ir

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
Street address
Esfand North, Farvardin, Ahvaz, Khuzestan province
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3311 0000
Email
aduaum@ajums.ac.ir
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

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Afsanehtalebi68@gmail.com

Position
Student

Latest degree
Master

Other areas of specialty/work
Midwifery

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

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Person responsible for updating data

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Position
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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