Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Examining the impact of family-based educational support programs on stigma and mental health in women who have experienced abortion.

Protocol summary

Study aim
Evaluation of a Family-Centered Educational Support Program's impact on stigma and mental health in women with abortion experiences.

Design
A clinical trial with a parallel control group was conducted on 60 women who had experienced miscarriages. The study was two-way blinded and randomized, with random allocation software utilized for randomization.

Settings and conduct
Field of Study: Behavioral Sciences This study aims to assess the effectiveness of a family-centered educational and supportive intervention in reducing psychological distress and perceived stigma related to miscarriage among women in Shahrekord, Iran 2023. A quasi-experimental pre-post test design will be used to compare the outcomes of an intervention group with those of a control group. This study features an 8-week, 60-minute family-centered educational program as the intervention. Participants in the intervention group will begin the program two weeks after experiencing a miscarriage, while the control group will receive standard care. Additionally, the husbands of participants in the intervention group will attend two educational sessions. Participants will complete questionnaires before the program starts, immediately after it ends, and again two months later.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Written informed consent; no history of elective abortion; no history of infertility. Exclusion Criteria: Unwillingness to continue participation; a history of recurrent miscarriages; becoming pregnant.

Intervention groups
The intervention group will participate in an eight-session educational and support program. Additionally, the spouses of participants will attend two in-person training sessions. The control group will receive standard post-miscarriage care.

Main outcome variables
Mental health and stigma.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180123038486N3**
Registration date: **2025-02-18, 1403/11/30**
Registration timing: **retrospective**

Last update: **2025-02-18, 1403/11/30**
Update count: **0**

Registration date
2025-02-18, 1403/11/30

Registrant information

Name
Ziba Raisi Dehkordi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 38 3224 0556

Email address
ziba758@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-21, 1403/03/01

Expected recruitment end date
2024-09-20, 1403/06/30

Actual recruitment start date
2024-05-21, 1403/03/01

Actual recruitment end date
2024-10-21, 1403/07/30

Trial completion date
2024-10-21, 1403/07/30

Scientific title
Examining the impact of family-based educational support programs on stigma and mental health in women who have experienced abortion.

Public title
Effect of a family-based education support program on stigma and mental health in women who have experienced abortion.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
At least 2 but no more than 3 months have passed since a miscarriage of a fetus less than 20 weeks gestation No experience of severe psychological trauma, such as the death of a close relative, within the past 3 months Written informed consent to participate in the study Age between 10 and 54 years No history of infertility Ability to read and write Absence of reported psychiatric disorders (as reported by the mother, no history of psychiatric medication use) No history of elective abortion Exclusion of miscarriages following assisted reproductive technology (ART) pregnancies

Exclusion criteria:
Unwillingness to continue cooperation participation in the educational-supportive program for more than two sessions during the research period. Incomplete completion of questionnaires. Use of counseling services outside of the research. No experience of severe psychological trauma (no reported traumatic events such as accidents or the death of a loved one) during the study Consumption of any type of tranquilizer, narcotic, or cigarette during the study Becoming pregnant. Divorce. History of recurrent miscarriage (two or more miscarriages)

Age
From **10 years** old to **54 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to either the intervention or control group using a block randomization method, generated by the Random Allocation software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant Data Analys

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Sahrekord Univercity of Medical Sciences

Street address
Number 4, Kashani Avenue, Shahrekord Univercity of Medical Sciences

City
shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
1383837181

Approval date
2024-04-30, 1403/02/11

Ethics committee reference number
IR.SKUMS.REC.1403.014

Health conditions studied

1

Description of health condition studied
Abortion

ICD-10 code
O03

ICD-10 code description
Spontaneous abortion

Primary outcomes

1

Description
Individual stigma scores from the miscarriage stigma questionnaire and mental health scores on the 21-item Depression, Anxiety, and Stress Scale (DASS-21).

Timepoint
At pre-intervention, post-intervention, and at the 8-week follow-up

Method of measurement
Individual-Level Abortion Stigma Questionnaire (ILAS) and the DASS-21 Mental Health Questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Received routine post-miscarriage care, which included eight 60-minute educational and supportive sessions, as well as two in-person educational sessions for their partners.
Category
Rehabilitation

2

Description
Control group: The control group received standard care, which included one follow-up appointment during the first week after the abortion and another session between one month and 40 days post-abortion. This care involved education on warning signs, post-abortion support, and parenting counseling for couples.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive Health Centers and Imam Ali Clinic, Shahrekord
Full name of responsible person
Ziba Raisi Dehkordi
Street address
Number 4, Kashani Avenue, Shahrekord Univercity of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Gholamreza Roshandel
Street address
Number 4, Kashani Avenue, Shahrekord Univercity of Medical Sciences
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vcrt@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Ziba Raisi Dehkordi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
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Position
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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
Not applicable
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
Specific information, such as primary outcomes or similar key results, may be shared when data sharing is limited.
When the data will become available and for how long
Data access will begin 6 months after the publication of the results
To whom data/document is available
Data will be available only to researchers affiliated with academic and scientific institutions
Under which criteria data/document could be used
For statistical analysis in systematic reviews and meta-analyses
From where data/document is obtainable
Dr. Ziba Raeisi Dehkordi ziba758@gmail.com 09133823763
What processes are involved for a request to access data/document
The requested data will be available within 2 weeks of contacting the designated individual via email or phone
Comments