

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 University of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8817846935

Phone

+98 38 3224 0556

Email

ziba758@gmail.com

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 University of Medical Sciences

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713471

Phone

+98 38 3224 0556

Email

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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Number 4, Kashani Avenue, Shahrekord University of Medical Sciences

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Phone

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Email

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Person responsible for scientific 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

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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**Person responsible for updating data****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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