Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effect of group counseling based on admission and commitment on mental health and post-abortion bereavement in women with spontaneous abortion

Protocol summary

Study aim

Study of the effect of group counseling based on admission and commitment on mental health and post-abortion bereavement in women with spontaneous abortion

Design

This study will be one-blinded, study population will be included all women with spontaneous abortion referring to Motazedi hospital of Kermanshah city. A total of 60 eligible women will be selected conveniently and randomly and assigned to two intervention and control groups.

Settings and conduct

This study, which will be conducted in Motazedi hospital of Kermanshah city is one- blinded. At the beginning of the study, the grief and general health after the abortion will be investigated. The grief and general health will be reassessed in both groups immediately and one month after (the intervention in intervention group), then two groups will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Wanted pregnancy; 2 months passed of spontaneous abortion; No history of infertility
Exclusion criteria: The incidence of adverse events and outcomes during the study;Use of medication during the study

Intervention groups

The intervention group, in addition to the routine care for spontaneous abortion, will receive the group counseling based on admission and commitment in 8 sessions of 90 minutes twice a week. The intervention will be done as soon as the participants be ready and within maximum one week after the abortion. The control group will receive only the routine care.

Main outcome variables

Grief after abortion; General Health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N105**
Registration date: **2018-11-07, 1397/08/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-07, 1397/08/16**
Update count: **0**

Registration date

2018-11-07, 1397/08/16

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 83 1821 4653
Email address
fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-02, 1397/07/10

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Study of the effect of group counseling based on admission and commitment on mental health and post-abortion bereavement in women with spontaneous abortion

Public title
The effect of group counseling based on admission and commitment on mental health and post-abortion bereavement in women

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of abortion based on sonography or gynecologist diagnosis; Wanted pregnancy; Spontaneous abortion under 20 weeks; 2 months passed from spontaneous abortion; General health scale scoring higher than 22.

Exclusion criteria:
Using medication during the study The incidence of unpleasant events during the study

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly by tossing coin

Blinding (investigator's opinion)
Single blinded

Blinding description
The Statistical analyzer is blind about allocation of study groups. In this way, the analyzer does not know which data belongs to the control or intervention group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2018-08-14, 1397/05/23

Ethics committee reference number
ir.kums.rec.1397.413

Health conditions studied

1

Description of health condition studied
Bereavement

ICD-10 code
Z63.4

ICD-10 code description
Disappearance and death of family member

Primary outcomes

1

Description
Bereavement after abortion

Timepoint
Before, after and one month after the end of the study

Method of measurement
Based on prenatal grief scale (PGS)

2

Description
Mental health

Timepoint
Before, after and one month after the end of the study

Method of measurement
Base on General Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group, in addition to the routine care for spontaneous abortion, will receive the group counseling based on admission and commitment for 8 sessions of 90 minutes twice a week. The intervention will be done as soon as the participants be ready and within maximum one week after the abortion.

Category
Behavior

2

Description
The control group will receive only the routine care.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Motazedi Hospital
Full name of responsible person
Shahin Sotoodeh
Street address
Ferdowsi Avenue, Motazadi Hospital
City
Kermanshah
Province
Kermanshah
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6715847141
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+98 83 3723 2343
Email
sh_so2de@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
City
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Postal code
6715847141
Phone
+98 83 3836 0014
Email
fnajafi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Shahin Sotoodeh
Position
Master's student counseling in midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery
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sh_so2de@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Sosan heydarpour
Position
Faculty Member of Kermanshah University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery
City
Kermanshah
Province
Kermanshah
Postal code

6715847141

Phone

+98 83 3826 6429

Email

s.heydarpour1394@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Shahin Sotoodeh

Position

Master's student counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Isar Square, Dolatabad Blvd, Faculty of Nursing and Midwifery

City

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Province

Kermanshah

Postal code

6715847141

Phone

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Email

sh_so2de@yahoo.com

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

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments