

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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)

##### Phone

+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  
**Postal code**  
6715847141  
**Phone**  
+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**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
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**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  
**City**  
Kermanshah  
**Province**  
Kermanshah  
**Postal code**  
6715847141  
**Phone**  
+98 83 3826 6429  
**Email**  
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**

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**Phone**

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**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**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3826 6429

**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**