

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The Effect of Structured Counseling of Midwife on Grief and Bereavement after Miscarriage

Protocol summary

Summary

Study objective: The aim of this study was to evaluate the effect of structured counseling a midwife on grief and bereavement after miscarriage. Design: This study was a randomized clinical trial with two groups (experimental and control), pre and post-test design, and not-blind. Setting and conduct: This study was conducted on 60 women hospitalized in women department of Omolbanin, Imam Reza and Ghaem hospitals of Mashhad that were randomly divided into two groups (n = 30). Inclusion criteria: 18-35 years old; Spontaneous abortion under 20 weeks. Exclusion criteria: withdraw from the study participation for any reason. Intervention: in experimental group was conducted structured counseling in two 90-minute session by the researcher immediately after abortion during hospitalization and in control group received routine educations (educational pamphlet). A telephone meeting was considered next week after second meeting. The main outcome variables in this study included: grief and bereavement that in both groups was assessed before the intervention, 4 and 8 weeks after the abortion with grief and bereavement questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022324469N1**

Registration date: **2016-09-13, 1395/06/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-13, 1395/06/23

Registrant information

Name

Maryam Alizadeh

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-08-23, 1395/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Structured Counseling of Midwife on Grief and Bereavement after Miscarriage

Public title

The Effect of Structured Counseling of Midwife on Grief and Bereavement after Miscarriage

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 18-35 years old; definitive diagnosis of abortion by ultrasound; Spontaneous abortion under 20 weeks. Exclusion criteria: withdraw from the study participation for any reason.

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

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Vice chancellor for research, Ghorashy Building, University St

City

Mashhad

Postal code

Approval date

2016-03-02, 1394/12/12

Ethics committee reference number

IR.MUMS.REC.94.877

Health conditions studied

1

Description of health condition studied

Grief

ICD-10 code

F43.2

ICD-10 code description

Adjustment disorders

2

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

Grief after miscarriage

Timepoint

Before the intervention, 4 and 8 weeks after the abortion

Method of measurement

Grief questionnaire after miscarriage

2

Description

Bereavement after miscarriage

Timepoint

Before the intervention, 4 and 8 weeks after the abortion

Method of measurement

Bereavement questionnaire after miscarriage

Secondary outcomes

1

Description

Bereavement after Miscarriage on women

Timepoint

Before the intervention, 4 weeks after the intervention, 8 weeks after intervention

Method of measurement

The questionnaire perinatal Bereavement

Intervention groups

1

Description

Intervention group: in intervention group was conducted structured counseling in two 90-minute sessions by the researcher immediately after abortion during hospitalization. A telephone meeting was considered next week after second meeting. Grief and bereavement of women was assessed before the intervention, 4 and 8 weeks after the abortion with grief and bereavement questionnaires.

Category

Behavior

2

Description

Control group: in this study, no intervention was administered to the control group and women received routine educations (educational pamphlet). Grief and bereavement of women in this group was assessed before the intervention, 4 and 8 weeks after the abortion with grief and bereavement questionnaires, too.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Omolbanin hospital

Full name of responsible person

Nahid Ebrahimi

Street address

Women Department, Omolbanin Hospital, Ayatollah
Bahjat St, Mashhad

City

Mashhad

2

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Elham Rezaee

Street address

Women Department, Imam Reza Hospital, Ebne Sina
St, Imam Reza Square, Mashhad

City

Mashhad

3

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Akram Arta

Street address

Women Department, GHaem Hospital, Ahmad Abad
St, Dr Shariati Square, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences, Vice
chancellor for research

Full name of responsible person

Mohsen Tafaghodi

Street address

Mashhad University of Medical Sciences, Vice
chancellor for research, Ghorashy Building,
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences, Vice chancellor
for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Maryam Ahmadi

Position

Master of Science Student in Midwifery

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty