Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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, Ghoraishy 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

Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Omolbanin hospital
Full name of responsible person
Nahid Ebrahimi
Street address
Women Department, Omolbanin Hospital, Ayatolah 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
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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
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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, Ghoraishy Building, University St
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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
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Person responsible for scientific inquiries

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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