Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of The Effect of Midwifery Consultation With Existential Approach and routine care On Prenatal Grief in mothers with pregnancy loss: a clinical trial

Protocol summary

Summary

The objective of this study is Comparison of The Effect of Midwifery Consultation with existential approach on prenatal grief in mothers with pregnancy loss. Fulfilment process: objective conditions and how the study is done, is explained for the selected individuals. According to blocks of four, they're randomly divided into intervention and control groups after filling informed consent. The control group receives routine care. Intervention group participates in weekly existential consultation sessions in addition to routine care. Inclusion criteria: presence of abortion, ectopic pregnancy, moles, stillbirth; at least junior high-school education; no depression background, psychological disorders or physical ailments; no participation in other medical programs; not receiving individual consultation or medication; informed consent to participate in the study. Exclusion criteria: elective abortion; unmarried individuals; under 18 individuals, drug abuse. The Primary outcome is complicated grif and and the secondary outcome is depression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082424339N1**
Registration date: **2017-10-19, 1396/07/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-19, 1396/07/27

Registrant information

Name

Ali Hadinfar

Name of organization / entity

Departeman of Biostatistic, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research; Shahroud University of Medical Sciences

Expected recruitment start date

2016-08-13, 1395/05/23

Expected recruitment end date

2017-09-11, 1396/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The Effect of Midwifery Consultation With Existential Approach and routine care On Prenatal Grief in mothers with pregnancy loss: a clinical trial

Public title

The effect of Midwifery Consultation on Prenatal Grief

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: presence of abortion, ectopic pregnancy, moles, stillbirth; at least junior high-school education; no depression background, psychological

disorders or physical ailments; no participation in other medical programs; not receiving individual consultation or medication; informed consent to participate in the study. Exclusion criteria: elective abortion; unmarried individuals; under 18 individuals, drug abuse.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Random allocation is done through block randomization with the blocks of size four. After obtaining informed consent people assigned to intervention and control groups according to determined table

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Central building of Shahroud University of Medical Sciences, Tir Square,Shahroud

City
Shahroud

Postal code
3614773955

Approval date
2016-04-12, 1395/01/24

Ethics committee reference number
IR.SHMU.REC.1394.18

Health conditions studied

1

Description of health condition studied
Psychological support in pregnancy

ICD-10 code
O26.9

ICD-10 code description
pregnancy-related condition unspecified

Primary outcomes

1

Description
Complicated Grif

Timepoint
Before the intervention, six weeks later, three months later

Method of measurement
Standard questionnaire of prenatal grief

Secondary outcomes

1

Description
Depression

Timepoint
Before the intervention, six weeks later, three months later

Method of measurement
Standard questionnaire of Wijma Delivery Expectancy/Experience(W-DEQ)

Intervention groups

1

Description
Control group: The control group will receive routine care.

Category
Behavior

2

Description
Intervention group: The intervention group will participate in existential sessions (6sessions,45-60 minutes) as well as receiving routine care.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Medical Sciences Hospitals

Full name of responsible person
Soheila Mirzabeigi

Street address
Central building of Shahroud University of Medical Sciences, Tir Square,Shahroud.

City
Shahroud

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research; Shahroud University of Medical Sciences
Full name of responsible person
Dr Mohammadhasan Emamian
Street address
Central building of Shahroud University of Medical Sciences, Tir Square,Shahroud.
City
Shahroud
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research; Shahroud University of Medical Sciences
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
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Position
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Person responsible for scientific inquiries

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Person responsible for updating data

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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*