

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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 grief 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
Shahroud University Of Medical Sciences

Full name of responsible person
Soheila Mirzabeigi

Position
Master Of Science Student In Midwifery Counseling

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person
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Faculty Member

Other areas of specialty/work

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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

