

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Effect of cognitive behavioral based counselling in post abortion grief

Protocol summary

Study aim

The effect of cognitive-behavioural counselling on post-abortion grief

Design

Two group clinical trial with control group, randomized, with a sample size of 84 persons per group

Settings and conduct

The cognitive-behavioural counselling group(group A) receive six 30-40 minute counselling sessions which will hold weekly in Imam Reza clinic . The sessions Contains of: The cognitive assessment, and agreement on the aim of therapy,.... ; while control group (group B) will receive routine care such as check of vital sign and bleeding . After counselling sessions finished all patients in both group will evaluate with prenatal grief scale and they will follow up 3 months later.

Participants/Inclusion and exclusion criteria

Inclusion critria:Women with positive history of spontaneous abortion or any other abortion, age over 18 years and ability to speak and understand Persian language. Exclusion criteria :Pregnancy, History of depression ,substance abuse,Mental disorder or chronic physical illness

Intervention groups

The cognitive-behavioural counselling group(group A) receive six 30-40 minute counselling sessions which will hold weekly . The sessions Contains of: The cognitive assessment, and agreement on the aim of therapy, Providing information about grief, its process and components, normalizing its emotional and behavioral consequences of grief process ("its normal to cry when one experience such a loss"), Identifying dysfunctional irrational beliefs and their emotional behavioral and physical consequences, Teaching and practicing adaptive rational thinking and functional emotional and behavioral consequences, Assist the bereaved in a search for ways to reorganize life without the deceased ; while control group (group B) will receive routine care such as check of vital sign and bleeding .

Main outcome variables

Post abortion grief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180407039223N2**

Registration date: **2018-12-30, 1397/10/09**

Registration timing: **prospective**

Last update: **2018-12-30, 1397/10/09**

Update count: **0**

Registration date

2018-12-30, 1397/10/09

Registrant information

Name

Leila Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5225 1581

Email address

leilabagheri94@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of cognitive behavioral based counselling in post abortion grief

Public title

Effect of counselling in post abortion grief

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Women with positive history of spontaneous abortion or any other abortion Age over 18 years Ability to speak and understand Persian language

Exclusion criteria:

History of depression Mental disorder Chronic physical illness Substance abuse Pregnancy Having suicidal thoughts or acting on it

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: **168**

Randomization (investigator's opinion)

Randomized

Randomization description

Current research has two control and counselling group and four block sampling will be used for random allocation . In this method six possible situations 1 AAB, 2AB, 3ABA, 4BAA, 5BA, 6BAA will exist. Participant will choose envelope which prepared by the methodologist and might be consist of any of 1-6 situations . By selecting the first envelope, the first to fourth participant will be placed in group A or B. Again, the next participant will select another envelope and it will be known who the fifth to eighth will be in the group and this procedure will continue.

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 Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences-Hafte Tir Square

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷۷۳۹۵۵

Approval date

2018-10-08, 1397/07/16

Ethics committee reference number

IR.SHMU.REC.1397.139

Health conditions studied**1****Description of health condition studied**

Post abortion grief

ICD-10 code

F43.29

ICD-10 code description

Adjustment disorder with other symptoms

Primary outcomes**1****Description**

Post abortion grief

Timepoint

Immediately after the end of consultation sessions and three months later

Method of measurement

Prenatal grief scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group : The cognitive-behavioural counselling group receive six 30-40 minute counselling sessions which will hold weekly in Imam Reza clinic . The sessions Contains of: The cognitive assessment, and agreement on the aim of therapy, Providing information about grief, its process and components, normalizing its emotional and behavioral consequences of grief process ("its normal to cry when one experience such a loss"), Identifying dysfunctional irrational beliefs and their emotional behavioral and physical consequences, Teaching and practicing adaptive rational thinking and functional emotional and behavioral consequences, Assist the bereaved in a search for ways to reorganize life without the deceased.

Category

Prevention

2

Description

Control group: will receive routine care such as check of vital sign and bleeding.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Leila Bagheri

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Dr.Dadman Ave , Dr.Dadman Blvd , Shahrjadic

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Web page address

<http://emamreza.larums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hasan Emamian

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Web page address

<http://www.shmu.ac.ir/fa>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Leila Bagheri

Position

Candidate PhD of reproductive health

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Leila Bagheri

Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable