Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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)
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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 AABB, 2ABBA ,3ABAB ,4BBAA ,5BAAB ,6BABA 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 , Shahrjadid
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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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Fax
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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
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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