Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Psychological Counseling on Grief and Post-Traumatic Stress Symptoms in Mothers After Stillbirth.

Protocol summary

Summary

Objectives: Study on effects of psychological counseling on grief and post-traumatic stress symptoms in mothers after stillbirth. Design: This is a semi-experimental study with the Pretest - Post test plan. The study population includes all women whose children were born dead during the last 1 to 4 weeks and have the inclusion criteria. The study population consist of 100 people. The selected individuals will be randomly divided in to the two groups of intervention and control. First, according to the number of the subjects, envelopes containing the names of the groups (A and B) will be randomly arranged and then based on the referring of the desired qualified people, one of the envelopes which determines the respective group will be allocated to each person. Then the questionnaires are explained by the researcher or her colleague and will be completed as a pretest. Four 90-minute sessions of psychological counseling grief will be formed in groups-individual by the researcher within two weeks for the intervention group in the related health centers. Four weeks after the last counseling session, questionnaires will be filled in both groups again as the post-test. In the end, booklet or CD containing educational content of the sessions will be provided to the control group if desired. Inclusion criteria: The recent history of stillbirth (1-4 weeks ago); Exclusion criteria: Being absent in more than one counseling session. Finally, the intensity of grief and post-traumatic stress of two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092629980N1**
Registration date: **2016-11-22, 1395/09/02**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-11-22, 1395/09/02

Registrant information

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Zahra Saravani
Name of organization / entity
Zahedan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Psychological Counseling on Grief and Post-Traumatic Stress Symptoms in Mothers After Stillbirth.

Public title

Effect of counseling on grief in mothers after stillbirth

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: The recent history of stillbirth (1-4 weeks ago); Older than 18 years; Literate; No history of infertility; The lack of stillbirth history in previous Pregnancies; The lack of psychiatric disorders and drug abuse history; The lack of first-degree relatives death experience or other severe crises in the last year. Exclusion criteria: Being absent in more than one counseling session; Crisis or death during the study.
Age
From **18 years** old
Gender
Female

Phase
2
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

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Science
Street address
University of Medical Sciences, Dr. Hesabi Square, Zahedan
City
Zahedan
Postal code
9816743463
Approval date
2016-05-15, 1395/02/26
Ethics committee reference number
IR.ZAUMS.REC.1395.65

Health conditions studied

1

Description of health condition studied
Post-traumatic stress disorder
ICD-10 code
F43.1
ICD-10 code description
Post-traumatic stress disorder

2

Description of health condition studied
stillbirth
ICD-10 code
Z37.1
ICD-10 code description
Single stillbirth

3

Description of health condition studied
grief
ICD-10 code
F43.2
ICD-10 code description
Adjustment disorders

Primary outcomes

1

Description
grief
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
PGS questionnaire

2

Description
post-traumatic Stress disorder
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
PPQ questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First, questionnaires will be filled in Intervention group as the pretest. Four 90-minute sessions of psychological counseling grief will be formed in groups-individual by the researcher within two weeks for the intervention group in the related health centers. Booklet or CD containing educational content of the sessions will be provided to the intervention group, too. Four weeks after the last counseling session, questionnaires will be filled in both groups again as the post-test.
Category

Rehabilitation

2

Description
Control group: First, questionnaires will be filled in Control group as the pretest. Control group will not receive any intervention except routine care. 6 weeks later the questionnaires will be refilled as post-test. In the end, booklet or CD containing educational content of the sessions will be provided to the control group if desired, as well.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ebne Abi Taleb Hospital in Zahedan

Full name of responsible person
Parvaneh Pahlavan

Street address
Ali Ebne Abi Taleb Hospital, Health Boulevard, Khalije Fars Boulevard, Zahedan

City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Zahedan University of Medical Sciences, Zahedan, Iran.

Full name of responsible person
Hoshang Rafigh Doost

Street address
University of Medical Science, Dr. Hesabi Square, Zahedan, Iran

City
Zahedan

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 of Zahedan University of Medical Sciences, Zahedan, Iran.

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
Faculty of Nursing & Midwifery of Zahedan

Full name of responsible person
Zahra Saravani

Position
Student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person
Dr. Ali Navidian

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Associate professor of Zahedan University of Medical Sciences

Other areas of specialty/work

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City
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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