Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of psychosocial education on anxiety and attachment of mother to fetus in pregnancy after stillbirth

Protocol summary

Summary

Aims: To study the effect of psychological training on anxiety and attachment of mother to fetus in post-partum pregnancy. Design: This is a semi-experimental study with pretest and posttest design. Population: Includes women who after the birth of a dead baby in pregnancy. Previously, they were pregnant again and have entry criteria. The sample size is 100 people randomly divided into two groups of intervention and control. At first, the total number of enrolled subjects will be provided with study groups (A intervention and B control) and will be arranged randomly. Gradually, by identifying the eligible person, one of the envelopes will be allocated to the selected individuals, respectively. The questionnaires will then be described by the researcher or his colleague and completed by the participants as a pretest. For the intervening intervention group, four sessions of the psychological training program Within 2 weeks and on the basis of the specified content, they will receive the educational materials during the sessions. After 6 weeks, the research questionnaires are completed as a post-test for both groups. Finally, the CD and the educational booklet are also given to the control group. Entry criteria: Pregnancy up to one year after the birth. Grades: Absence or absence of more than one training session. Ultimately, the anxiety and maternal attachment to the fetus are compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017110429954N6**
Registration date: **2017-11-09, 1396/08/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-09, 1396/08/18

Registrant information

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Ali navidian
Name of organization / entity
Zahedan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source
Deputy of Research and Technology of Zahedan University of Medical Sciences

Expected recruitment start date

2017-06-15, 1396/03/25

Expected recruitment end date

2017-11-16, 1396/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of psychosocial education on anxiety and attachment of mother to fetus in pregnancy after stillbirth

Public title

The effect of psychological training on anxiety and attachment of mother after stillbirth

Purpose

Supportive

Inclusion/Exclusion criteria
Entry criteria: Age over 18 years old pregnant mother - Pregnancy up to one year after gestational age and non-pregnancy-High-risk pregnancy-Multiple pregnancies-No experience of stillbirth more than one time or abortion - One pregnancy 20-30 weeks -No existence Known psychiatric disorders and lack of addiction-lack of psychosocial crisis, such as the death of loved ones or the occurrence of serious problems and serious illness in the last 6 months. Exit criteria: Incidence of pregnancy problems (bleeding, runny nose, preeclampsia), admission and termination of pregnancy-absence or absence of more than one training session

Age
No age limit

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zahedan University of Medical Sciences

Street address
Zahedan University of Medical Sciences, Dr. Hesabi Square

City
Zahedan

Postal code
9816743463

Approval date
2017-06-12, 1396/03/22

Ethics committee reference number
IR.ZAUMS.REC.1396.56

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F41.1

ICD-10 code description
Generalized anxiety disorder

2

Description of health condition studied
Mother's attachment to the fetus

ICD-10 code
F94.2

ICD-10 code description
Disinhibited attachment disorder of childhood

3

Description of health condition studied
Stillbirth

ICD-10 code
Z37.1

ICD-10 code description
Single stillbirth

Primary outcomes

1

Description
Mother's attachment to the fetus

Timepoint
Before intervention and 6 weeks after intervention

Method of measurement
Cranly questionnaire

2

Description
Anxiety

Timepoint
Before intervention and 6 weeks after intervention

Method of measurement
PRAQ-17 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First, the questionnaires are completed as a pre-test. For the intervention group, the researcher will have four sessions of psychological training in a group-community for two weeks at the relevant health / health center and will be provided with CDs and educational materials. Six weeks later, the questionnaires will be filled in again as a post-test

Category
Rehabilitation

2

Description
Control group: First, the questionnaires are completed as a pre-test. The control group will not receive any intervention other than routine care, after 8 weeks, the post-test will be given and, if desired, the CD control group and other training materials will be given to them.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Center for Comprehensive Health Services
Full name of responsible person
Ms. Salari
Street address
In front of Majdieh 23
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research of Zahedan University of Medical Sciences
Full name of responsible person
Normohammad Bakhshani
Street address
Zahedan University of Medical Sciences, Dr. Hesabi Square
City
Zahedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research of Zahedan 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
Nursing and Midwifery Faculty of Zahedan
Full name of responsible person
Mehrnegar Azogh
Position
MSc Student
Other areas of specialty/work
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Person responsible for updating data

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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