

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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

Name

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of Research of Zahedan University of Medical Sciences

Full name of responsible person

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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

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Position

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Web page address**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