

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Spiritual Self-Care on Distress and Anxiety of Stillbirth Mothers

Protocol summary

Distress, Anxiety

Study aim

Determining the Effect of Spiritual Self-Care on The Level of Distress and Anxiety of Stillbirth Mothers

Design

This study is a clinical trial that has a control and intervention group and will be performed without blinding. Participants are randomly drawn into groups. The number of samples is predicted to fall to 60 people. After the formation of the groups, a spiritual self-care package will be designed based on the interventions of Richards and Bergin (1997) with an Islamic approach. Data collection will be done through two questionnaires of Beck anxiety and Simmons and Gahr distress tolerance and data analysis will be done using SPSS version 26.

Settings and conduct

In the intervention group, 6 sessions of spiritual self-care with Islamic approach were held individually within two weeks and each session lasted 30 to 40 minutes.

Participants/Inclusion and exclusion criteria

Research population: All stillbirth women admitted to the gynecology ward of hospitals under the auspices of the University Inclusion criteria: stillbirth, minimum literacy, no physical and mental illness, no use of psychedelics, drugs and narcotics Exclusion criteria: unwillingness to participate in the study and withdrawal from the meetings

Intervention groups

Intervention: 6 sessions of spiritual self-care are held individually within two weeks. Because these mothers are hospitalized for about 2 to 3 days, the first two sessions will be in person and the rest of the sessions will be by phone-video. The sessions will last 30-40 minutes and the presentation will be in the form of lectures, questions and answers, telling stories and anecdotes appropriate to the topic and giving exercises. Control group: First, the questionnaires are completed as a pre-test. Control: They only receive routine care.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211007052692N1**

Registration date: **2021-10-16, 1400/07/24**

Registration timing: **prospective**

Last update: **2021-10-16, 1400/07/24**

Update count: **0**

Registration date

2021-10-16, 1400/07/24

Registrant information

Name

Fatemeh Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4429 5764

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-06-20, 1401/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Spiritual Self-Care on Distress and Anxiety of Stillbirth Mothers

Public title

The Effect of Spiritual Self-Care in Stillbirth Mothers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Birth of a stillborn baby Gestational age after 24 weeks
Minimum literacy No chronic physical and mental illness
No history of drug use, psychedelics and narcotics

Exclusion criteria:

Reluctance to participate in the study Withdraw from participating in self-care programs

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly drawn in the study groups. In this way, after examining the eligible patients and obtaining the satisfaction of the patients, a lottery container with 2 numbers (intervention) and 2 (control) is randomly taken out by the researcher, which indicates the number. Is the group in which it is placed. If the number of samples in each group is completed, that number will be removed from the lottery and this will continue until the required number of samples for both study groups is completed.

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

Mashhad University of Medical Science

Street address

Ibn Sina Street, doctora intersection

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2021-09-14, 1400/06/23

Ethics committee reference number

IR.MUMS.NURSE.REC.1400.047

Health conditions studied

1

Description of health condition studied

Stillbirth

ICD-10 code

Z37.1

ICD-10 code description

Single stillbirth

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after the intervention, 3 weeks after the intervention

Method of measurement

Beck Anxiety Questionnaire

2

Description

Distress

Timepoint

Before and after the intervention, 3 weeks after the intervention

Method of measurement

Simmons and Gahr Emotional Distress Tolerance Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the questionnaires are completed as a pre-test and 6 sessions of spiritual self-care are held individually within 2 weeks. Because these mothers are hospitalized for about 2 to 3 days, the first two sessions will be in person and the rest of the sessions will be by phone-video. The sessions will last 30-40 minutes and the presentation will be in the form of

lectures, questions and answers, telling stories and anecdotes appropriate to the topic and giving exercises. The questionnaires were completed again at the end of the intervention and 3 weeks after the end of the intervention time.

Category

Behavior

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. Questionnaires are completed again 3 weeks later.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Fatemeh Karimi

Street address

Ibn Sina St, Imam Reza Hospital Square

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2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Hazrat Umm Al-Banin Women's Hospital

Full name of responsible person

Fatemeh Karimi

Street address

Corner of Ayatollah Behjat 16- Hazrat Umm Al-Banin Women's Hospital

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4

Recruitment center

Name of recruitment center

Mehr Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayyur Mobarehan

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Karimi

Position
Masters Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Ph.D.

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Nursery

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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

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

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

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

Data Dictionary

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