Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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
Distress, Anxiety

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
karimif992@mums.ac.ir

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

City

Mashhad

Province

Razavi Khorasan

Postal code

۹۱۳۷۹۱۳۳۱۶

Phone

+98 51 3854 3031

Email

karimif992@mums.ac.ir

2

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Fatemeh Karimi

Street address

Ahmadabad St, Ghaem Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

99199-91766

Phone

+98 51 3845 3239

Email

karimif992@mums.ac.ir

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

City

Mahhad

Province

Razavi Khorasan

Postal code

۹۱۴۴۷۳۴۷۶۷

Phone

+98 51 3223 1061

Email

karimif992@mums.ac.ir

4

Recruitment center

Name of recruitment center

Mehr Hospital

Full name of responsible person

Fatemeh Karimi

Street address

Al-Nandasht Square, Mehr Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

۳۸۴۰۰۴۶۸

Phone

+98 51 3842 7014

Email

karimif992@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayyur Mobarehan

Street address

University St

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 1538

Email

vcresraech@mums.ac.ir

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

Street address
Ibn Sina Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3859 1511

Email
karimif992@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Naghmeh Razaghi

Position
Faculty member

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Ibn Sina Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3859 1511

Email
razaghin@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Karimi

Position
Master Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Ibn Sina Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 51 3859 1511

Email
karimif992@mums.ac.ir

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