Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of spiritual care based on the Sound Heart Model on the anxiety and burden of care in mothers of children with cancer

Protocol summary

Study aim
The effect of spiritual care on the stress and burden of caring for mothers of children with cancer

Design
Quasi- experimental with a control group,

Settings and conduct
For the intervention group, 8 sessions of 20 to 30 minutes in person and groups of 3 to 5 people will be taken and the manual provided by the Spiritual Counseling Counselor will be given to the mothers of the intervention group at the stage of providing spiritual care. Then, immediately and one month after the end of the eighth session the Beck Anxiety and Bargaining Questionnaire will again be completed by the participants in the intervention and control group. It should be noted that there is no intervention for the control group and they will be under the usual care of the department. inventory will be completed by the mothers of the group at the beginning of the study and 4 weeks later. At the end of the study, the package will be provided to the participants of the control group.

Participants/Inclusion and exclusion criteria
B Muslim; passed at least 6 months from the diagnosis of a child's illness; failure to have mental illness; awareness of childhood disease; absence in the same sessions and classes; the child's presence and presence at least 10 days in the department; lack of other stressful events other than childhood during the past year.

Intervention groups
For the intervention group, 8 sessions of 20 to 30 minutes are performed face to face in groups of 3-5 women, and the instruction book provided by the Spiritual Counseling Counselor in the stage of providing spiritual care is given to the mothers of the intervention group at the first session. The control group also receives section routines.

Main outcome variables
Spiritual care

General information

Reason for update

Acronym
cancer

IRCT registration information
IRCT registration number: **IRCT20160119026104N4**
Registration date: **2018-12-16, 1397/09/25**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-16, 1397/09/25**
Update count: **0**

Registration date
2018-12-16, 1397/09/25

Registrant information

Name
Mahnaz Shoghi

Name of organization / entity
Iran university of medical sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-23, 1397/08/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of spiritual care based on the Sound Heart Model on the anxiety and burden of care in mothers of children with cancer

Public title
Effect of spiritual care on the anxiety and burden of care in mothers of children with cancer
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Be Muslim Passed at least 6 months from the diagnosis of a child's illness Awareness of childhood disease Absence in the same sessions and classes The child's presence and presence at least 10 days in the ward
Exclusion criteria:
History of psychological illness Other stressful events other than childhood during the past year-
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Tehran, Valiasr Ave., higher than Vanak Square, Rashidiassemi Avenue, Iran Nursing Midwifery Faculty
City
Tehran
Province
Tehran
Postal code
1996713883
Approval date
2018-08-26, 1397/06/04
Ethics committee reference number
IR.IUMS.REC.1397.359

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Burden of care
Timepoint
The beginning of the study (before the study began) and one month later
Method of measurement
Zarit's Care Load Questionnaire

2

Description
Anxiety
Timepoint
The beginning of the study (before the study began) and one month later
Method of measurement
Beck Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
A total of 86 children with cancer who are eligible to participate in the study will be selected using the available method and will be included in the study. After explaining the actions and obtaining the informed consent, in the first stage, "before intervention," the anxiety and care of the mothers of both intervention groups And control is measured by questionnaires. The second stage of "intervention" will be based on the model of the spiritual heart of the spiritual care. For prevention of inflammation, the information of the control group from a hospital and the intervention group will be selected from the other hospital. This intervention during the childhood admission of children in the hospital during the days when the conditions of the child, mother and child are allowed to run every day, which includes 8

sessions of 20 to 30 minutes in groups of 3-5 people, and a booklet prepared from the Spiritual Counseling Paper at the presentation stage Spiritual care was given to the mothers of the intervention group, and then they were given the first hearing of the Qur'an and the music of the rain, and they will be asked to listen to it through headphones or hangfra. The music is given to them and they are asked to listen to it every day. After the completion of the sessions, anxiety and emergency care questionnaires will be completed immediately and after one month by the intervention group participants. It should be noted that there is no intervention for the control group and they will be under the usual care of the department. At the end of the study, a manual will be provided and the voice packet will be provided to the control group participants

Category

Other

2

Description

Control group: Spiritual Care Booklet and Audio Pack

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Childrens medical center

Full name of responsible person

Tahereh Mohamadzadeh

Street address

Number 62, Childrens Medical Center, Dr. Qarib street, Keshavarz blvd.

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1511419733

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2

Recruitment center

Name of recruitment center

Hazrat Ali Asghar Hospital

Full name of responsible person

Soroor Sohrabi

Street address

Ali Asghar hospital, Shahid Dasgerdi street

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Province

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1919816766

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soroor.soh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seid Kazam Malakuti

Street address

School of Nursing and Midwifery, Shahid Yasemi Street., North Kordestan Highway., Tehran., IRA

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PR@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mahnaz Shoghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Tehran, Valiasr Ave, above Vanak Square, Rashid Yasemi Ave., Iran Nursing Midwifery Faculty

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
After Data coding in order to keep the confidentiality of the participants in the research.

When the data will become available and for how long
The end of sampling till six months after article publishing.

To whom data/document is available
Ethical, Reviewer and Editorial committees, Researchers.

Under which criteria data/document could be used
Systematic review and meta-analysis or secondary analysis citation

From where data/document is obtainable
Mahnaz Shoghi, Email: shoghi.m@ums.ac.ir

What processes are involved for a request to access data/document
After sending a request to academic email, we will send our data files up to one week.

Comments