Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of spiritual care training based on "Ghalbe Salim" model on self-efficacy in care and caregivers burden in mothers with leukemia children reffering to Imam Reza (AS) clinic of Shiraz University of Medical Sciences- 2020

Protocol summary

Study aim
Determining of spiritual care training based on "Ghalbe Salim" model on self-efficacy in care and caregivers burden in mothers with leukemia children reffering to Imam Reza (AS) clinic of Shiraz University of Medical Sciences

Design
Interventional study before and after with the control group, with the parallel group, stage 2-3 on 64 mothers. To determine the permutation block sample (four), then demographic information, care pressure questionnaire and self-efficacy questionnaire are provided to both groups and the latest data are analyzed with SPSS software.

Settings and conduct
64 mothers with leukemia children (school age) reffering to Imam Reza (AS) clinic who are divided into two groups of 32 intervention and control using random method and permutation block method, then demographic information form, self-efficacy in care and caregivers burden to people in both groups as a pre-test. After that, the intervention group was given spiritual care training based on "Ghalbe Salim" in 4 sessions of 30 minutes, and then the self-efficacy in care and caregivers burden is done as a post-test and finally the data will be analyzed with SPSS software

Participants/Inclusion and exclusion criteria
Doing the mother's job as a caregiver Child age between 6 to 12 years Being a Muslim Have a minimum of basic education The mother is not physically or mentally ill Lack of experience of a stressful event in the last 6 months Must be able to speak Persian

Intervention groups
In the intervention group, mothers receive spiritual care training based on "Ghalbe Salim" in 4 sessions of 30 minutes, but in the control group, no intervention will be performed.

Main outcome variables
self-efficacy in care and caregivers burden in mothers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210410050924N1**
Registration date: **2021-05-04, 1400/02/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-05-11, 1400/02/21**
Update count: **1**

Registration date
2021-05-04, 1400/02/14

Registrant information

Name
Zahra Sharifi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-30, 1400/02/10

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of spiritual care training based on "Ghalbe Salim" model on self-efficacy in care and caregivers burden in mothers with leukemia children reffering to Imam Reza (AS) clinic of Shiraz University of Medical Sciences- 2020

Public title
The effect of self-efficacy-based spiritual care training on the care and care pressure of mothers with leukemia children
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Perform motherly duties as a caregiver The child is between 6 and 12 years old Being a Muslim The mother does not have a mental illness The mother must be able to speak Persian Mother Have at least primary education Lack of experience of a stressful event in the last 6 months
Exclusion criteria:
Death of a child or mother during the intervention period Immigrating to another country The mother's unwillingness to continue cooperating in the study
Age
From **6 years** old to **12 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the researcher collects samples in a quadratic block method. In this way, each person who enters the study based on the permutation table identifies two groups of intervention and control as follows: control group A and intervention group B, and each block of 4 different shapes of placing A, B and There are generally 6 different modes that are numbered from 1 to 6. By rolling the dice, it is determined which order to choose. The researcher takes samples according to the specified order. He then rolls the dice again and executes another command. In the same way, continue sampling to reach the desired number.
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
Ethics Committee of Shiraz University of Medical Sciences
Street address
Shiraz, Zand St., Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
88916-15859
Approval date
2021-03-03, 1399/12/13
Ethics committee reference number
IR.SUMS.REC.1399.1311

Health conditions studied

1

Description of health condition studied
Leukemia
ICD-10 code
C91
ICD-10 code description
Lymphoid leukemia

Primary outcomes

1

Description
self-efficacy in care
Timepoint
Before intervention, after intervention
Method of measurement
Zhang Care Self-Efficacy Questionnaire

Secondary outcomes

1

Description
care and caregivers burden
Timepoint
Before intervention and after intervention
Method of measurement
Novak and Gost Care Pressure Questionnaire

Intervention groups

1

Description

The intervention group, individually in 4 sessions for 30 to 45 minutes in each session and once a week, spiritual care is provided by the researcher using a booklet related to this care, including: Communication with God , With others, with yourself, with the environment, as approved by the tutor. In each session, one of the four aspects of human beings will be discussed and the educational booklet that the researcher has made based on the model of spiritual care based on the "Ghalbe Salim" model will be given to mothers in the same session.The researcher will also contact the mothers during the week and remind them of the implementation of spiritual care. One week after the end of the fourth intervention session, self-efficacy questionnaires in care and care pressure will be given to mothers as a post-test for the effect of the fourth session.

Category

Other

2

Description

No special intervention will be done for the control group, but at the end of the study, in order to comply with the ethical standards, spiritual care educational pamphlets based on the " Ghalbe Salim" model will be provided to the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
clinic of Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Soleymani
Street address
Specialized and sub-specialized clinic of Imam Reza (AS), next to Namazi Hospital, Namazi Square, Shiraz
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shiraz 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
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Position
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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable