

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Spiritual Support on caregiver's stress and quality of life of children aged 8 to12 with leukemia

Protocol summary

Summary

This study is a randomized clinical trial with a design of two pre-test and post-test groups aimed at determining the effect of the spiritual support on the caregiver's stress and the quality of life in children aged 8 to 12 suffering from Leukemia hospitalized in Oncology ward of Dr. Sheikh hospital. The studied population consists of the children aged 8 to 12 suffering from acute Lymphoblastic Leukemia hospitalized in Mashhad Dr Sheikh hospital and their caregivers. Inclusion criteria: Having informed written consents, Having Iranian citizenship, Residing in Mashhad and the surrounding areas, Having literacy, Not suffering from known mental illnesses, A confirmed diagnosis of Acute lymphoblastic leukemia by doctor. Exclusion criteria: The unwillingness of the individual to participate in the study, Occurrence of an emergency interfering situation in the continuation of the project, Receiving a comprehensive educational program. Sample size was considered 30 persons in each group and all together about 60 persons. In this study, intervention is 5 sessions enjoying spiritual support given by an investigator and supervised by a religious expert. Instructions will be through speeches, asking and answering questions, group discussions and distribution of the printed version of the materials presented in each session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052425713N1**

Registration date: **2016-08-08, 1395/05/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-08, 1395/05/18

Registrant information

Name

Elham Zafarian

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 51 3341 4883

Email address

zafarianme921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Spiritual Support on caregiver's stress and quality of life of children aged 8 to12 with leukemia

Public title

The Effect of Spirituality on caregiver's stress and quality of life of children with leukemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Having informed written consents,

Having Iranian citizenship, Residing in Mashhad and the surrounding areas, Having literacy, Not suffering from known mental illnesses, A confirmed diagnosis of Acute lymphoblastic leukemia by doctor. Exclusion criteria: The unwillingness of the individual to participate in the study, Occurrence of an emergency interfering situation in the continuation of the project, Receiving a comprehensive educational program.

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

By randomized table

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for research, Ghoraishy Building, University St, Mashhad

City

Mashhad

Postal code

91375345

Approval date

2016-05-14, 1395/02/25

Ethics committee reference number

IR.MUMS.REC.1395.74

Health conditions studied

1

Description of health condition studied

Leukemia

ICD-10 code

D72.8

ICD-10 code description

Other specified disorders of white blood cells

Primary outcomes

1

Description

Caregiver's stress

Timepoint

Before and after the intervention

Method of measurement

DASS questionnaire

Secondary outcomes

1

Description

Quality of life of children

Timepoint

Before and 1 month after the intervention

Method of measurement

Teenagers'quality of life questionnaire

Intervention groups

1

Description

No intervention is made for control group

Category

N/A

2

Description

Intervention group: will participate in 5 sessions of sixty minutes each day based on Richards and Bergin pattern focusing on the Islamic rituals and including psycho-spiritual components such as: prayer, trust and appeal, patience, gratitude and forgiveness. In the first session, participants will be asked to put forward their supportive needs in terms of personal experience. During the second session caregivers will be familiar with the role of trust and appeal in getting along with psychological stress caused by child disease and will be trained to know the theoretical bases of trust and appeal, trust as a contrastive strategy to deal with stress, ways to achieve the trust and appeal and How one can use trust and appeal as effective contrastive strategy to convert inappropriate negative excitements to negative excitements. In the third session the role of prayer in

solving their problems and the impact of prayer on the process of problem solving is discussed. Also some instructions will be given about the value and importance of prayer, its philosophy, familiarity with the correct practical way of praying, And familiarity with the effects of prayer on the relationship of the individual with God, oneself and others. In the fourth session they will be familiar with the concept of thanksgiving and its effect on reducing negative excitements and effective beliefs will be taught about thanksgiving's effect to decrease caregivers' negative excitements and in the last session they will be familiar with the steps of patience and they will be taught about the value of patience, kinds of patience, steps of patience and patience as a strategy to deal with the pressures caused by the child's illness.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Sheikh hospital

Full name of responsible person

Hava Abdollahi

Street address

Taheri St, Tohid Square, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Vice Chancellor for research, Ghorashy Building,
University St, Mashhad

City

Mashhad

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

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

Mashhad University of Medical Sciences

Full name of responsible person

Elham Zafarian

Position

Master Student

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Doctora Crossroads,
Mashhad

City

Mashhad

Postal code

Iran

Phone

+98 51 3341 4883

Fax

Email

zafarianme921@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

HamidReza Behnam Vashani

Position

Faculty of Nursing and Midwifery, master in nursing

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Ebne Sina St,
Doctora Crossroads, Mashhad

City

Mashhad

Postal code

Phone

+98 51 3859 1511

Fax

Email

BehnamHR@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Elham Zafarian

Position

Master Student

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Doctora Crossroads,
Mashhad

City

Mashhad

Postal code

Iran

Phone

+98 51 3341 4883

Fax

Email

zafarianme921@mums.ac.ir

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