

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of peer education on quality of life of family caregivers of children with leukemia

Protocol summary

Summary

The aim of this study was to determine the effect of peer education on quality of life of caregivers that they were family members of children with leukemia. Inclusion criteria for children in this research was they must be at least one course of chemotherapy and their age between 1-7 years; for caregivers their age have to more than 18 years. Exclusion criteria was death in children during the study and withdrew caregivers from continuing to participate in the study. The study population consisted of caregivers of children with leukemia in two center of blood Ali Asghar Hospital and Children's Medical Center. Number of participants in intervention and control group was 34 and 37 people respectively. This study was held pre-test at baseline and post-test one month after the last intervention. Intervention to the experimental group was trained caregivers with peer group that includes 4 sessions of 60 minutes in a row, in the form of lectures and group discussions, and each group consisting of 5 to 10 people, by those trained in small groups held a friendly environment. The control group was considered normal care without any intervention. Persian version of quality of life questionnaire was used to assess intervention in this research.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021232522N1**
Registration date: **2017-06-14, 1396/03/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-14, 1396/03/24

Registrant information

Name

Simin Valinezhad Alvar

Name of organization / entity

University of Iran Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6557 7001

Email address

valinezhad.s@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, School of Nursing and Midwifery

Expected recruitment start date

2016-10-01, 1395/07/10

Expected recruitment end date

2017-08-01, 1396/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of peer education on quality of life of family caregivers of children with leukemia

Public title

Quality of life for caregivers of family members of children with leukemia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: children must be at least one course of chemotherapy; having a primary caregiver in the family; age between 1-7 years; workers have more than 18

years; have the ability to speak; read and write; lack of any chronic mental disorder. exclusion criteria: carers member of the peer group; a history of participating in training programs on child's illness; death in children during the study; withdrew workers from continuing to participate in the study; the absence of more than one session training class in carers member groups.

Age

From **1 year** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **71**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Iran Medical Sciences

Street address

Besides Milad Tower Tehran Highway martyr Hemmat

City

Tehran

Postal code

1449614535

Approval date

2016-05-28, 1395/03/08

Ethics committee reference number

IR.IUMS.REC1395.9211196243

Health conditions studied

1

Description of health condition studied

leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukaemia

Primary outcomes

1

Description

Quality of life

Timepoint

before intervention, one month after intervention

Method of measurement

Caregivers of people with cancer quality of life questionnaire (CQOLC - P)

Secondary outcomes

1

Description

we don't have any secondary measure

Timepoint

we don't have any secondary outcome time point

Method of measurement

we don't have any secondary outcome method of measurement

Intervention groups

1

Description

There was no intervention in the control group and at the same time with the intervention group the quality of life questionnaire at baseline and one month after the last training session was given to them.

Category

Treatment - Drugs

2

Description

Intervention program include two weeks, two sessions per week and 60 minutes per session. The program was performed in groups. Each group contains 8 to 10 people. In intervention group, instructions was taught by trained peers from sources which researcher given to them in the form of booklets, pamphlets and PowerPoint . The Quality of Life Questionnaire at baseline and one month after the last training session was given to the intervention group.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Simin Valinezhad Alvar

Street address

Tehran Keshavarz Blvd. Street doctor Gharib next to
Imam Khomeini Hospital Children's Medical Center

City

Tehran

2

Recruitment center

Name of recruitment center

Hazrat Ali Asghar hospital (AS)

Full name of responsible person

Simin Valinezhad Alvar

Street address

City

Tehran Shariati Street martyr Dastagird (Zafar)

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Nursing University of Medical Sciences Of
Iran

Full name of responsible person

Dr. Nahid Akbari

Street address

Tehran Vali Asr Street Vanak Street martyr Rashid
Yassami University's School of Nursing and Midwifery

City

Tehran

Grant name

Grant code / Reference number

9211196243

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

Yes

Title of funding source

School of Nursing University of Medical Sciences Of Iran

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

School of Nursing and Midwifery, Iran University of
Medical Sciences

Full name of responsible person

Simin valinezhad Alvar

Position

Children's Nursing Graduate Student

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Facultymember of Iran University of Medical Sciences

Full name of responsible person

Dr. Sedigheh Khanjari

Position

Director of nursing children and newborns

Other areas of specialty/work

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Position

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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