

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of coping skills training on quality of life and sense of coherence in parents of children with leuckemia

Protocol summary

Summary

This study is a quasi-experimental clinical trial before and after (pretest – posttest) with the control group. In this study parents who meet the inclusion criteria and refer to oncology clinic of Medical Center of Children and Bahrami Hospital assign as control group and parents who refer to Ali Asghar and Mofid Hospital assign as experimental group. The samples are selected using convenience sampling. After explaining the purpose and method of the study, consent form to be complete by the subjects participating in the study. For the experimental group coping skills training including social communication skills will perform through four, 2 hours sessions for 4 consecutive weeks (one session per week). Education will be performed by small group discussion (5-8 members) and presenting by using PowerPoint. Session for each group at the hospital will be held on separate days. After the end of sessions, to the experimental group will be take the relevant educational pamphlets. The control group receives only the routine education of the hospitals. Data will be collected through three questionnaires including demographic characteristics, The Caregivers Quality of Life Index Cancer-Persian and The Sense of Coherence-13. For the control group the data will be collected through two phases pretest and posttest (four week later). The questionnaires will be completed through three phases: before, immediately and four weeks after the intervention in the experimental group. After data collection, the control group will be received educational pamphlets.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062313748N1**

Registration date: **2013-08-01, 1392/05/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-01, 1392/05/10

Registrant information

Name

Sedigheh Khanjari

Name of organization / entity

Iran University of Medical Sciences, Tehran, Iran

Country

Iran (Islamic Republic of)

Phone

00982188211861, 00982166927171

Email address

s-khanjari@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Tehran University of Medical Sciences

Expected recruitment start date

2013-02-23, 1391/12/05

Expected recruitment end date

2013-07-24, 1392/05/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of coping skills training on quality of life and sense of coherence in parents of children with leuckemia

Public title

The effect of coping skills training on quality of life and sense of coherence in parents of children with leuckemia

Purpose

Other

Inclusion/Exclusion criteria
Inclusion criteria: Children aged 1-16 years; have experienced at least one course of chemotherapy; having a main family caregiver (father or mother); the parents being older than 18 years; knowing how to read and understand the Persian language; not having a history or current psychiatric or neuropsychological disorders; never having been diagnosed with cancer of any type in close family member; residing in Tehran and Alborz. Exclusion criteria: Occurrence and perceived stress of major life events (divorce, financial crisis, death of a family member); Participation in a special education.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
N/A

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

Vice chancellor for research Tehran University of Medical Sciences

Street address

Ghods St., Keshavarz Ave., Tehran

City

Tehran

Postal code

Approval date

2013-02-04, 1391/11/16

Ethics committee reference number

130/2868/91/3

Health conditions studied

1

Description of health condition studied

leukemia

ICD-10 code

C91, C92

ICD-10 code description

Lymphoid leukaemia, Myeloid leukaemia

Primary outcomes

1

Description

Quality of Life

Timepoint

Immediately and four weeks after the intervention

Method of measurement

The Caregivers Quality of Life Index Cancer- Persian

2

Description

Sense of Coherence

Timepoint

Immediately and four weeks after the intervention

Method of measurement

Sense of Coherence-13

Secondary outcomes

empty

Intervention groups

1

Description

For the experimental group coping skills training including social communication skills will perform through four, 2 hours sessions for 4 consecutive weeks (one session per week). Education will perform by group discussion (discussion in small groups consist of 5-8 members) and presenting by using powerpoint. Session for each group at the hospital, will be held on separate days. After the end of sessions, to the experimental group will be take the relevant educational pamphlets.

Category

Other

2

Description

The control group receive only the routine education of the hospitals.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Childrens Medical Center Hospital

Full name of responsible person

Street address

No.62, Next to Imam Khomeini Hospital, Doctor
Mohammad Gharib St., Keshavarz Ave., Tehran

City

Tehran

2

Recruitment center

Name of recruitment center

Ali Asghar Hospital

Full name of responsible person

Street address

Vahid Dastgerdi Martyr St.(Zafar), Ayatollah Modares
Highway, Tehran

City

Tehran

3

Recruitment center

Name of recruitment center

Bahrami Children's Hospital

Full name of responsible person

Street address

Kayani Martyr St., Damavand St., Imam Hossein Sq,
Tehran

City

Tehran

4

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Street address

Front of Ershad Hosseinih, Dr. Shariati St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Tehran University of
Medical Sciences

Full name of responsible person

Sedigheh Khanjari

Street address

Ghods St., Keshavarz Ave., Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research Tehran 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

Iran University of Medical Sciences

Full name of responsible person

Sedigheh Khanjari

Position

Faculty Member / Assistant Professor

Other areas of specialty/work

Street address

Next to Milad Tower, Hemmat Martyr Highway,
Tehran

City

Tehran

Postal code

Phone

+98 21 8821 1861

Fax

Email

s-khanjari@tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Sedigheh Khanjari

Position

Professor Assistant

Other areas of specialty/work

Street address

Next to Milad Tower, Hemmat Martyr Highway,
Tehran

City

Tehran

Postal code

Phone

+98 912 738 7239

Fax

Email

s-khanjari@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Somayeh Borji

Position

Nursing MSc Student

Other areas of specialty/work

Street address

Ghods St., Keshavarz Ave., Tehran

City

Tehran

Postal code

Phone

+98 912 841 5116

Fax

Email

s-borji@razi.tums.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