

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of family-centered empowerment model on knowledge and caring performance of mothers of children with leukemia

Protocol summary

Study aim

The effect of family-centered empowerment model on knowledge and caring performance of mothers of children with leukemia

Design

The clinical trial has a control group, with parallel and randomized groups, and a sample size of 62 mothers with children with leukemia.

Settings and conduct

the study population includes mothers of children with cancer who referred to the oncology department of Baqaei2 hospital. the researcher will start sampling by receiving a letter of introduction. Then by random division in to even and odd numbers they are placed in two groups of test and control. The questionnaire will be given to the samples and then the data will be analyzed. in the next step the intervention is done using educational contents.

Participants/Inclusion and exclusion criteria

inclusion criteria: one of the primary caregivers should be with the patient and live with him, children between the ages of 2 and 12, the primary caregiver will be able to answer questions, participate in research and have the necessary cooperation, at least six months have passed since the diagnosis of disease. Exclusion criteria: lack of willingness to cooperate, failure to attend at least one training session, failure to complete questionnaires, acute problems include bleeding, severe infection, and other issues that prevent the patient and his caregiver from cooperating

Intervention groups

In the intervention group, the family-centered empowerment model will be implemented in four steps (perceived threat, self-efficacy enhancement, self-esteem and process evaluation) that will consist of 5 sessions (two sessions per week). The control group received no intervention

Main outcome variables

knowledge and caring performance of mothers of

children with leukemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200325046857N1**

Registration date: **2020-06-08, 1399/03/19**

Registration timing: **retrospective**

Last update: **2020-06-08, 1399/03/19**

Update count: **0**

Registration date

2020-06-08, 1399/03/19

Registrant information

Name

Fateme Boshagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4265 4418

Email address

f.boshagh2016@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of family-centered empowerment model on knowledge and careing performance of mothers of children with leukemia

Public title
The effect of family-centered empowerment pattern on blood cancer in children

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Live with the patient from the primary caregiver and with the patient The age of the child includes 2 years to 12 years. The main caregiver of the family has the ability to answer questions and be able to participate in research and collaboration At least six months have passed since the diagnosis
Exclusion criteria:
Lack of willingness to cooperate Do not attend at least one training session Do not complete questionnaires Acute problems include bleeding, severe infection, and other issues that prevent the patient from working with him or her

Age
From **2 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **62**

Randomization (investigator's opinion)
Randomized

Randomization description
samples will be arranged numerically and then randomly divided in to even and odd numbers in two groups of test and control.

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 Ahvaz Jundishapur University of

Medical Sciences
Street address
Golestan St
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2019-08-06, 1398/05/15
Ethics committee reference number
IR.AJUMS.REC.1398.312

Health conditions studied

1

Description of health condition studied

leukemia

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description

knowledge ,careing performance

Timepoint

Before the intervention, two months after the intervention

Method of measurement

Specific questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The questionnaire is then distributed among the samples and after analyzing the data, the first step (before the intervention) leads to identifying the limitations, needs and weaknesses of caregivers in various fields. Then, in the second step, the intervention will be done using the educational content of the face. Training takes place in 5 sessions of 45 minutes (two sessions per week). At the end of each session, prepared pamphlets will be provided to patients and their families.

Category

Rehabilitation

2

Description

Control group: The control group did not receive any

intervention
Category
N/A

Country of origin
Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Baq'a'i Hospital 2
Full name of responsible person
Fateme Boshagh
Street address
Azadegan Ave
City
Ahvaz
Province
Khouzestan
Postal code
15794 -61357
Phone
+98 61 3222 2818
Email
f.boshagh2016@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
دکتر محمد بدوی
Street address
Golestan St
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3222 2818
Email
f.boshagh2016@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ashrafal sadat Hakim
Position
Faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Golestan St
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3373 8622
Email
hakim-a@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
fateme boshagh
Position
MSc student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
MSc student
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Phone
+98 61 3222 2818
Email
f.boshagh2016@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person

Fateme boshagh

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Golestan St

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Phone

+98 61 3222 2818

Email

f.boshagh2016@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available