Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

Study aim
The effect of family-centered empowerment model on knowledge and careing 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: lake 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 careing 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
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Iran (Islamic Republic of)
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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

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqa'i Hospital 2

Full name of responsible person

Fateme Boshagh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

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

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

Country of origin

Type of organization providing the funding

Academic

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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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
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