

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The effect of Family-centered empowerment model on quality of life in patients with leukemia

Protocol summary

Summary

This study aimed to determine the effect of family-centered empowerment model on the quality of life in patients with leukemia is designed. In this study patients after informed consent and based on inclusion and exclusion criteria and were enrolled to achieve the desired volume and random numbers table using into control and test groups(46 patients with 46 patients in each group). Inclusion criteria were age older than 18 years, the company's ability and literacy tests, and patient and family exclusion criteria are not satisfied, the condition worsens and the inability to participate in the study sample. After dividing the sample into two groups, empowerment model on test was carried out. In the intervention group test in three groups of 12 subjects (6 cases and 6 careful) and a group of 10 people (five patients and five caregivers) were divided into family-centered empowerment model for each group 6 5/1 hour session and week two once implemented, lecture and question and answer sessions were conducted. The training of family-centered empowerment model (with the threat perceived self-efficacy, self-esteem and evaluation) were used. At the end of each session prepared pamphlets for the meeting was provided to patients and families. Also attended follow-up was performed in a hospital or by phone; in the control group received no intervention. Posttest 1/5 months after the intervention in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015021621100N1**

Registration date: **2016-06-14, 1395/03/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-14, 1395/03/25

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research Ahvaz University of Medical Sciences

Expected recruitment start date

2014-09-06, 1393/06/15

Expected recruitment end date

2014-11-01, 1393/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Family-centered empowerment model on quality of life in patients with leukemia

Public title

The effect of family empowerment model of leukemia patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria :1. The age of the patients older than 18 years. 2. mentally able to have the test . 3. The family is the primary caregiver familiar with Persian language and literacy have. 4. Take care of the family 's ability to answer questions and be able to participate in the research and collaboration . 5. Telephone addresses are catching up . 6. The training class is not the same company . 7. The medical history of psychiatric disorders , cognitive disorders , and other disorders is not .Exclusion criteria : 1. unwillingness to continue the cooperation of the patient or primary caregiver . 2. having severe problems , such as bleeding , infection and other problems that cause the inability of the patient or admission to the ICU . 3. At least not in session .

Age

From **18 years** old to **139 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The samples using random numbers table were assigned to two experimental and control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee OF Ahvaz University of Medical Sciences

Street address

Ethics Committee OF Ahvaz University of Medical Sciences, City University, Ahvaz

City

Ahvaz

Postal code

61357-15794

Approval date

2014-09-06, 1393/06/15

Ethics committee reference number

ajums.REC.1393.166

Health conditions studied

1

Description of health condition studied

leukaemia disease

ICD-10 code

C91.0 , C9

ICD-10 code description

lymphoplasmacytic lymphoma.acute exacerbation of chronic myeloid leukaemia

Primary outcomes

1

Description

Quality Of Life

Timepoint

pretest. 1/5 month of posttest

Method of measurement

Quality Of Life-Cancer Survivor

Secondary outcomes

empty

Intervention groups

1

Description

The aim of this study was to determine the effects of education on quality of life for leukemia patients is the teaching of family-centered empowerment model was done. The test was conducted on a group of family-centered empowerment model. In the case group in three groups of 12 subjects (6 cases and 6 careful) and a group of 10 people (five patients and five caregivers) were divided along routine mice, a model of family-centered empowerment for each Group 6 1.5 Meeting hour and was performed twice a week, lecture and question and answer sessions were conducted. At the end of each session prepared pamphlets for the meeting was provided to patients and families.

Category

Rehabilitation

2

Description

The study also controls for monitoring the impact of the empowerment model was applied on the testl group But education and routine clinical care received.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Thalassemia and hemoglobinopathies Research
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research 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
Vice Chancellor for research Ahvaz 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

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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