Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of Educational Intervention Based on the Family-Centered Empowerment Model on the Burden of Care and Quality of Life of Family Caregivers of Patients with Leukemia

Protocol summary

Study aim

Determining the effect of education based on the family-centered empowerment model on the caregiving burden and quality of life of family caregivers of patients with leukemia

Design

The present study is a quasi-experimental study with pretest-posttest and with a control group and an intervention group. The research units were entered into the study by continuous sampling method and were divided into two intervention and control groups. The required sample size at a confidence level of 95%, a power of 80%, and a precision of 8 was calculated according to previous studies as 33 people in each group, which was estimated to be 31 people in each group after considering sample attrition.

Settings and conduct

The family-centered empowerment model was used. The researcher designed an educational booklet for the intervention group on caring for patients with leukemia. The intervention group sessions were conducted in 7 sessions of 60-90 minutes during the four steps of the model during the caregivers' visits to the hospital and in groups of 7-8 people of the main caregivers, using group discussion and question and answer methods, and with educational aids such as educational booklets and PowerPoint files in the Firouzgar Hospital. The control group received only routine training in the ward.

Participants/Inclusion and exclusion criteria

Care for the patient for at least 4 hours a day and care for the patient's first-degree family member; Unwillingness to participate in the study

Intervention groups

The intervention group's training sessions were conducted through the four steps of the family-centered empowerment model with the participation of the patient's primary caregivers. The control group samples only used the usual training in the ward provided by the clinical nurses.

Main outcome variables

burden of care, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250118064426N1**
Registration date: **2025-02-20, 1403/12/02**
Registration timing: **retrospective**

Last update: **2025-02-20, 1403/12/02**
Update count: **0**

Registration date

2025-02-20, 1403/12/02

Registrant information

Name

Fatemeh Rashidi

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

2024-04-24, 1403/02/05

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

2024-04-26, 1403/02/07

Actual recruitment end date

2024-09-21, 1403/06/31

Trial completion date

2024-09-21, 1403/06/31

Scientific title

Investigating the Effect of Educational Intervention Based on the Family-Centered Empowerment Model on the Burden of Care and Quality of Life of Family Caregivers of Patients with Leukemia

Public title

Effect of the Family-Centered Empowerment Model on Family Caregivers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The caregiver must have the ability to understand and learn the study material. The caregiver must be between the ages of 18 and 60. The caregiver is a close family member of the patient (father/mother, sister/brother, spouse/child). The caregiver must be involved in patient care for at least 4 hours a day. The caregiver has not participated in other similar training programs. The caregiver should not have a disabling physical or mental disorder (based on the individual's self-report). The patient the caregiver is caring for is undergoing chemotherapy or has recently received it (at least within the last 3 months). The patient the caregiver is caring for is an adult (18-60 years old). The patient being cared for by the caregiver is not in the inpatient ward (selected from among those referred to the blood clinic).

Exclusion criteria:

Incompletely completed questionnaires Absence of more than one training session Having any disabling physical or mental problem during the intervention as determined by the doctor Unexpected events such as migration or death of caregiver/patient Reluctant to participate in the study.

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: **66**

Actual sample size reached: **63**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Vice President for Research and Technology, Central Headquarters Building, Iran University of Medical Sciences, Hemmat Highway, next to Milad Tower, Tehran.

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2024-04-13, 1403/01/25

Ethics committee reference number

IR.IUMS.REC.1403.018

Health conditions studied

1

Description of health condition studied

Leukemia

ICD-10 code

C81-C96

ICD-10 code description

Malignant neoplasms, stated or presumed to be primary, of lymphoid, haematopoietic and related tissue

Primary outcomes

1

Description

care burden

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Novak and Guest Caregiver Burden Questionnaire

2

Description

quality of life

Timepoint

Before the intervention and one month after the intervention

Method of measurement

Cancer Caregiver Quality of Life Questionnaire (CQOLC)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After approving the proposal and receiving the code of ethics with the ID (IR.IUMS.REC.1403.018), the researcher obtained the sampling introduction letter and submitted it to the Firoozgar Educational and Medical Center, and after introducing and explaining the research objectives and research implementation method to the relevant authorities, obtained their consent to conduct sampling. Then, the researcher designed an educational booklet on caring for cancer patients for the intervention group samples based on up-to-date evidence by reviewing reliable texts and references. Before sampling, each research unit was given a full explanation of the research objectives. A written informed consent form was provided if they wished to participate in the study. Sampling continued from April to September 2024.The intervention group sessions were scheduled in a four-step program (perceived threat, improving self-efficacy, improving self-esteem through educational participation, and evaluation) in 7 60-90 minute sessions during hospital visits and were conducted as group sessions of 7-8 people with the participation of the patient's primary caregivers (selected based on entry criteria) in the form of lectures, discussions, and question and answer sessions, using educational aids such as whiteboards, educational booklets, and PowerPoint presentation files in the Firouzgar Hospital training classroom by the researcher. This study used the family-centered empowerment model to achieve the goals. This model results from qualitative grounded theory research that, after going through the stages of forming concepts, developing concepts, identifying the psychosocial process of the problem, and resulting in the central variable (family-centered empowerment), went through the modeling stages to create an applied model. The implementation stages of the model include four steps: Step One (Perceived Threat): To examine the perceived threat, attention was paid to two aspects. The first aspect is perceived severity, which includes content related to managing complications and risks of the disease or disease treatments, focusing on (a) infection control, (b) prevention and treatment of mucositis, (c) control of nausea and vomiting, (d) alopecia, (f) diarrhea, (g) bleeding, (h) anemia, and (c) pain control and relief, and was taught to them using group discussion and educational booklets over 3 60-minute sessions. The second aspect is perceived sensitivity, which empowers the caregiver to answer, "How at risk am I as a caregiver for complications from caregiving?" This empowerment was a set of information and skills that were applied to the caregivers' needs in a 60-90 minute session to reduce and prevent complications and risks from caregiving on the caregivers themselves and included skills for controlling anxiety and depression, relieving fatigue, relieving physical problems of the caregiver, resolving problems and concerns related to the period of disease recurrence, and eliminating feelings of guilt and blame in the caregiver with the help of a clinical psychologist. The content provided in this step is as follows: First session: • Initial assessment and introduction to caregivers• Explanation of the study process, including the number and method of holding educational sessions and the necessity of not missing more than one session• Obtaining a written informed consent form• Providing a demographic information form, the quality of life questionnaire for caregivers of patients with cancer and the burden of care by Novak and Guest. Second session (perceived severity):• Familiarizing caregivers with the concept of cancer and leukemia, including:• Types of leukemia• Causes of leukemia• Symptoms caused by the disease• How to diagnose and treat• Treatment measures and methods• Complications caused by the disease and their management (fatigue and intolerance to activity, anemia, bleeding, impaired mental image, body pain and bone pain)• The role of diet and physical activity in the fight against cancer• Familiarity with warning signs and danger signs and how to access health-treatment centers in case of danger signs. Third session (perceived severity):• What is chemotherapy? And how is it done?• Introduction to chemotherapy side effects and the caregiver's role in controlling and managing them, including:• Identifying signs of infection and how to prevent infection• Strategies for maintaining oral mucosa health and controlling chemotherapy-induced mucositis• Strategies for improving appetite in patients• Strategies for controlling nausea and vomiting• Strategies for maintaining skin tissue health and integrity following radiotherapy and chemotherapy• Measures for chemotherapy-induced alopecia and changing mental image• Changes in bowel habits (diarrhea/constipation) due to chemotherapy and how to manage them• Management of fatigue and activity intolerance• Prevention and control of bleeding due to decreased blood cells following chemotherapy• Pharmacological and non-pharmacological strategies for pain control. Session Four (Perceived Sensitivity):• Review and management of side effects of caregiving on caregivers and how to manage them, including:• Skills for controlling anxiety and depression in caregivers• Relieving emotional fatigue in caregivers• Resolving physical problems in caregivers• Resolving feelings of guilt and blame in caregivers• Resolving problems and concerns related to the relapse period. Step Two (Improving self-efficacy): In the fifth session, caregivers were asked to share their experiences and information about the treatment process, assessment, and control of chemotherapy side effects for 60-90 minutes. Other topics discussed in this session are ways to prevent infection, control and relieve pain, improve self-control, experience applying the items taught in the educational sessions in dealing with the patient and their problems, and support other family members. Step Three

(Increasing Self-Esteem Through Educational Participation): In this stage (session six), in a 60-90 minute session, after reviewing the topics discussed in the previous sessions, caregivers were asked to participate in educating their patients in the field of recognizing and managing issues related to leukemia and the complications resulting from its treatment, and to encourage them to help themselves; in such a way that they transfer the topics discussed in each group discussion session to their patients and get feedback from them; Then, the caregivers were asked to write down the questions they had in this regard on a sheet of paper and submit them to the researcher; in this way, all the caregivers' notes were received and reviewed, and by doing so, the researcher could understand how successful the caregivers were in transferring educational materials to the patients, and the points that the caregivers had not transferred to the patients were discussed, and if the patients had any questions, they were answered. Step Four, Evaluation: The final evaluation was conducted one month after the last empowerment session for the experimental and control groups. After one month of implementing the program, during a return visit to the hospital or, if there was no return visit, online (by online questionnaire), the questionnaires were again provided to the experimental group and completed.

Category

Other

2

Description

Control group: The research units in control groups just used the usual ward training. This training included educational pamphlets available to all patients and caregivers, educational posters posted on the ward wall with topics related to cancer, and training provided by clinical nurses. After one month of implementing the program, during a return visit to the hospital or, if there was no return visit, online (by online questionnaire), the questionnaires were again provided to the control group and completed. The prepared educational booklet was also made available to the control group samples after receiving the post-test.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences Firoozgar Hospital

Full name of responsible person

Dr. Mohsen Khaleghian

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Firoozgar Hospital, Beh Afarin St., Karim Khan Zand Blvd., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Vice chancellor for Research and Technology, Iran University of Medical Sciences

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5th floor of the central headquarters, Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran.

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Rashidi

Position

Master's degree student in medical-surgical nursing

Latest degree

Bachelor

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long
The access period can begin 6 months after the results are published.

To whom data/document is available
The data will be available to researchers in academic and scientific institutions, and people working in other industries can also apply to receive them.

Under which criteria data/document could be used
Using data for scientific purposes.

From where data/document is obtainable
To receive data, please contact the study's principal investigator (Fatemeh Rashidi). Email address for correspondence: frashidi.nursing@gmail.com

What processes are involved for a request to access data/document
After requesting and conducting the necessary checks, the data is provided to the applicant as soon as possible (usually less than a week).

Comments