Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of a family need based program on caregivers burden of leukemia patients

Protocol summary

Summary

The effect of a family need based program on caregivers burden of leukemia patients. Introduction: Nowadays, most of the chronic cares (e.g. Cancer) are done at homes and by family caregivers. Given the diverse problems of the disease and its chronic progression, most of the patients and their families are not aware of the coping ways and do not receive proper supporting services, and the family of cancer patients because of their care roles, meet burden.Therefore it is essential that proper and effective intervention to decrease burden.Research Methodology :This study is based on a clinical trial in two groups and three stages. After demanding the recommendation letter from the department of Nursing and Midwifery of Isfahan University of Medical Sciences, the researcher referred to the management of hospital to present the purpose of the study and to start the sampling. The Seyed Al Shohada University Hospital (related to Isfahan University of Medical Sciences) are selected as scope of the study for the data collection. The data collection process is done from the family members who are the main caregivers and are responsible for all supports. The samples were selected randomly and then categorized into two groups named as experimental and control. The methodology of the study is quantitative approach and the survey study (two part questionnaire) is selected for the data collection. Sample of the Study the all family members of leukemia patients including male and female who refer to hospital and meet the criteria of the study. Sample of the study: The sample size of the study is 32 persons which is the result of consultation with the specialists of statistics. The data collection instrument in this study is two questionnaires which the first one includes two parts (A and B). Part A is related to demographic information of caregiver including (sex, age, marital status, education level, employment, relation to the patient, and the duration of caregiving) and the patient including (age, sex, marital status, education level, employment, duration of sickness). Part B contains the questions regarding the evaluation of burden of ZARIT caregiver which includes 22 items which the scales of each item are as follows: • Never: 0, The lowest score of healthcare • Seldom:1 • Usually :2• and Sometimes burden is 3 • Always :4 . 0 which means there is no burden. The highest score is 88 which means the highest rate of burden. The score between 61-88 means severe burden.The score between 31-60 is the average burden. The score under 30 is the slight burden. Finally data will analyzed with SPSS (version 20).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013093011895N2**
Registration date: **2014-05-06, 1393/02/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-06, 1393/02/16

Registrant information

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Narjes Khosravi
Name of organization / entity
Isfahan medical university
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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences and researcher

Expected recruitment start date
2013-04-07, 1392/01/18
Expected recruitment end date
2013-09-09, 1392/06/18
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of a family need based program on caregivers burden of leukemia patients

Public title
The effect of a family need based program on caregivers burden.
Purpose
Supportive
Inclusion/Exclusion criteria
All family members of ALL & AML patients including male and female who refer to Seyed Al Shohada University Hospital and meet the criteria of the study are constructing the sample of the study. Inclusion criteria: 1-The leukemia patients (ALL & AML). 2-From each family member who is the main caregiver is participated in the study. 3-Interested in study. 4-Age of over 18. 5-Able to communicate and comply with the rules of training sessions. 6-The caregiver is just taking care of one patient refractory in the family. 7-Capable of speaking, reading and writing in Farsi. 8-Have not participated in family education sessions (any research study in this field). 9-The main caregiver does not under psychotropic medication. The criteria of excluding: 1.The family caregiver is reluctant to cooperate in training sessions. 2.Existence of any problem that the caregiver is not able to participate in the study. 3.The caregiver has at most two absents in session records. 4.There are physical and psychological problems that cannot attend the sessions.
Age
From **18 years** old to **95 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
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 Isfahan University of Medical Sciences
Street address
Hezarjerib St, Isfahan
City
Isfahan
Postal code
8174673461
Approval date
2012-09-22, 1391/07/01
Ethics committee reference number
392057

Health conditions studied

1

Description of health condition studied
Acute lymphoblastic leukaemia and Acute myeloblastic leukaemia
ICD-10 code
C91.0, C92
ICD-10 code description
Acute lymphoblastic leukaemia [ALL], myeloblastic leukaemia [AML]-Acute myeloblastic leukaemia, minimal differentiation

Primary outcomes

1

Description
Family caregiver burden
Timepoint
before, immediately after, and a month after intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In this study,intervention is a family educational-supportive intervention based on a scheduled multi-session program with families and main caregivers to consider their needs and problems, and also to study the current articles which are gathered by the researcher,

that finally is planned under the supervision of specialists and the lecturers for an educational-supportive intervention for the study group that based on the availability of caregivers there would be five sessions (each session 90 minutes) during five weeks (one week one session). The main caregivers are grouped in minimum 8 to maximum 12 persons which the contents of sessions are same for all groups. The intervention begins with some comments on leukemia and how it affects the life of patient and the family. Some details regarding the symptoms of leukemia and disorders and also the effects of these problems on patient and family are expressed. The family will gain some information regarding the potential factors in causing or aggravating of this disease like environmental-familial stresses, nutrition, physical activities, and also genetics. The role of family communication skills, feeling expressions,coping with negative emotions, reduction of stress and anxiety techniques to caregivers, problem solving techniques, and the utilization of them towards the needs rectification of caregiving roles are provided by providing information for caregivers, which there will be an open discussion by the end of each session. Also, in order to strengthen of learning CDs and educational books are provided which would be the same for control group.

Category

Other

2

Description

Control group: Only learning CDs and educational books are provided

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed Al Shohada University Hospital (related to Isfahan University of Medical Sciences)

Full name of responsible person

Narjes «hosravi

Street address

Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Narjes Khosravi

Street address

No. 3, Block 31 employees, Martyr Montazeri Town, Tehran Road, Isfahan.

City

Isfahan

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, Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Narjes Khosravi

Position

Master of Science in Psychiatric Nursing

Other areas of specialty/work

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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