Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Effect of Peer Support-Based Online Education Program on the Burden of Care and Quality of Life of Patient's Family with Leukemia

Protocol summary

Study aim
To determine the effect of Peer Support-Based Online Education Program on the Burden of Care and Quality of Life of Patient's Family with Leukemia

Design
A none randomized clinical trial in two groups of intervention and control 80 participants divided into 40 people for each group will be done on family caregiver's of patient's with leukemia over a month

Settings and conduct
The study will be done in Shariati hospital where is one of the most significant center for hematology malignancy in Iran. successful peer families will be selected by the help of hematology and oncology head nurses and general self-efficacy questionnaire. The peer families will be educated in two sessions on an online platform. Afterward, a group will be established on social media to discuss and share the experience with other patient's leukemia caregivers. The researcher will educate caregivers to take care of patients through this group

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient's primary caregiver The caregiver should be at age of 18 or over The caregiver should be literate Have an access to social media and smartphone Consent participation in research Exclusion criteria: Caregiver addiction Having a distinct mental disorder of the caregiver Taking sedative medicine by caregiver

Intervention groups
The following research is about peer support-based online education programs on patient's families with Leukemia. The intervention group will receive online support from other families who have the same experience of caring for a leukemia patient. In addition, caregivers will be educated through social media platforms by researcher. The control group will receive ward care routines by nurses and doctors

Main outcome variables
Leukemia, burden of care, quality of life, online, peer, peer support, family of patient's with leukemia

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210507051209N1**
Registration date: **2021-07-18, 1400/04/27**
Registration timing: **prospective**

Last update: **2021-07-18, 1400/04/27**
Update count: **0**

Registration date
2021-07-18, 1400/04/27

Registrant information
Name
Mehrnaz Keramatikerman
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 3322 9951
Email address
me.keramati@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-08-11, 1400/05/20
Expected recruitment end date
2021-09-11, 1400/06/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
The Effect of Peer Support-Based Online Education Program on the Burden of Care and Quality of Life of Patient's Family with Leukemia

Public title
Effect of Peer Support-based online education on family patients with leukemia

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patient's primary caregiver The caregiver should be at age of 18 or over The caregiver should be literate Have an access to social media and smart phone Consent participation in reaserch

Exclusion criteria:

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: **80**

Randomization (investigator's opinion)
Not 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 Tehran University of Medical Sciences

Street address
4th floor, No 19, Ataei alley,1st street, D block, Valfajr, Afsariyeh

City
Tehran

Province
Tehran

Postal code
1786956635

Approval date
2021-06-20, 1400/03/30

Ethics committee reference number
IR.TUMS.FNM.REC.1400.049

Health conditions studied

1

Description of health condition studied
Plasma cell Leukemia

ICD-10 code
C90.1

ICD-10 code description
Plasma cell leukemia

Primary outcomes

1

Description
The proportion of caregivers emotional of burden is less than 20% in zarit questionnaire

Timepoint
Before initiating the study and a month later of intervention

Method of measurement
Zarit Burden questionnaire

2

Description
The proportion of caregivers quality of life is at most 140 in CQOLC-P questionnaire

Timepoint
Before initiating the study and a month later of intervention

Method of measurement
The Caregiver Quality of Life Index–Cancer

Secondary outcomes

1

Description
Score of care burden

Timepoint
Before initiating and a month later intervention

Method of measurement
Zarit Burden Interview

2

Description
Score of quality of life

Timepoint
Before initiating and a month later intervention

Method of measurement
CQOLC-P

Intervention groups

1

Description
Intervention group: The caregivers will received peer support-based online education program by 5 peer supports who are educated by researcher. The education study will be continued for a month and the sessions will be held 4 days a week in 2 hours. The researcher will answer caregivers questions and peer supports share their common experiences in the social media platforms. Peer supports will be chosen among 2 men and 3 women
Category
Rehabilitation

2

Description
Control group: The caregivers only will be received routine care by nurses in the wards
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Mehrnaz Keramatikerman
Street address
4th floor, No19, Ataei alley, 1st street, D block, Valfajr, Afsariyeh
City
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+98 21 3322 9951
Email
me.keramati@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammadali Sahraeian
Street address
Qods street, Keshavarz Blv,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653911
Phone
+98 21 6641 9084
Email
aasohrabpour@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mehrnaz Kermatikerman
Position
M.Sc of Medical-Surgical Nursing Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
4th floor, No 19, Ataei alley, block D, 1st street, Valfajr, Afsariyeh
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mehrnaz Keramatikerman
Position
MS.c of Medical-Surgical Nursing Student

Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Position
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Latest degree
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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
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
Yes - There is 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
Title and more details about the data/document
Certain participants information like age, gender, education, and relative relationship to the patients will be shared
When the data will become available and for how long
Data access will be available after 6 months
To whom data/document is available
University researchers, faculty members, and nursing staff working in a hospital
Under which criteria data/document could be used
Mention the name of authors
From where data/document is obtainable
Private email, academic email, mobile phone number, post address
What processes are involved for a request to access data/document
Ask for using data and mention authors names
Comments