

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

peer support, family of patient's with leukemia

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,

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

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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

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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 Keramatikerman

Position

M.Sc of Medical-Surgical Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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me.keramati@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mehrnaz Keramatikerman

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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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