

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of continuous virtual counseling on care burden and quality of life of family caregivers of patients with leukemia

Protocol summary

Caregivers' burden and quality of life

Study aim

Determining the effect of ongoing virtual counseling on the burden of care and quality of life of leukemia patients' family caregivers

Design

The present study is a randomized, two-group clinical trial that will be conducted with 90 family caregivers of leukemia patients. Participants will be selected using convenience sampling and will be divided into two control and experimental groups by simple randomization.

Settings and conduct

This study is a two-group randomized clinical trial involving 90 caregivers of leukemia patients in Hamadan. The intervention group will participate in six virtual counseling sessions, held weekly for 45 to 60 minutes. Caregiver burden and quality of life questionnaires will be administered one month and two months after the final session. The control group will receive only standard training.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having informed consent to enter the study, at least three months have passed since their patient's leukemia diagnosis by a specialist doctor, access to mobile phone and cyberspace, and age over 18. Exclusion criteria: Death of leukemia patients, and handing over patient care to another person.

Intervention groups

In the intervention group, the researcher will conduct six virtual counseling sessions, one per week for 45 to 60 minutes. These sessions will cover topics such as understanding leukemia, self-care, healthy eating, sleep hygiene, time management, stress reduction, positive adjustment, improving social relationships, and accessing social and financial support. Caregiver burden and quality of life questionnaires will be administered one and two months after the final session. The control group will receive only routine training.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211227053551N7**

Registration date: **2025-02-09, 1403/11/21**

Registration timing: **retrospective**

Last update: **2025-02-09, 1403/11/21**

Update count: **0**

Registration date

2025-02-09, 1403/11/21

Registrant information

Name

Vahid Yousofvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3252 6339

Email address

v.yousofvand@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

2021-10-07, 1400/07/15

Actual recruitment end date

2022-06-22, 1401/04/01

Trial completion date

2022-06-22, 1401/04/01

Scientific title

The effect of continuous virtual counseling on care burden and quality of life of family caregivers of patients with leukemia

Public title

The effect of virtual counseling on the burden of care and quality of life of caregivers

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent to enter the study At least three months have passed since their patient's leukemia diagnosis by a specialist doctor Access to mobile phone and cyberspace Age over 18 years

Exclusion criteria:

Death of patients with leukemia Handing over the patient's care to another person

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, the patients' caregivers will be assigned to two groups according to the determined sample size (90 people), according to the registered entry criteria, and using the block method (the 2-block method will be used; we will place the two letters A and B with different permutations in the blocks, randomly select 45 blocks, and assign each block to 2 people).

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 Hamadan University of Medical

Sciences

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2021-08-21, 1400/05/30

Ethics committee reference number

IR.UMSHA.REC.1400.394

Health conditions studied

1

Description of health condition studied

Leukemia

ICD-10 code

C90.1

ICD-10 code description

Plasma cell leukemia

Primary outcomes

1

Description

Caregivers' care burden

Timepoint

One month and two months after intervention

Method of measurement

Novak and Gast care burden questionnaire

2

Description

Caregivers' Quality of Life

Timepoint

One month and two months after intervention

Method of measurement

Cancer patients caregivers' quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, follow-up virtual counseling sessions will be held by the researcher for 6 sessions, 1 session per week for 45 to 60 minutes. The content of these sessions includes familiarizing caregivers with the nature of leukemia, taking responsibility for themselves, a healthy diet, sleep hygiene and time management, reducing stress and

positive adjustment, improving interpersonal and social relationships, and familiarizing them with sources of social and financial support and specific social networks. Caregiver burden and quality of life questionnaires will be administered one month and two months after the last care session.

Category

N/A

2

Description

Control group: The control group will receive only the usual training.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Amir Sadeghi

Street address

Eram Boulevard - Shahid Beheshti Hospital, Hamadan

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38698-65178

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+98 81 3838 0283

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ambegrad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Ali Reza Soltanian

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

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soltanian@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Amir Sadeghi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Amir Sadeghi

Position

Associate professor

Latest degree

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

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Full name of responsible person

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Position

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Other areas of specialty/work

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City

Hamadan

Province**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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