Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

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
Caregivers' burden and quality of life

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

City
Hamadan

Province
Hamadan

Postal code
38698-65178

Phone
+98 81 3838 0283

Email
ambehrad@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

City
Hamedan

Province
Hamadan

Postal code
38698-65178

Phone
+98 81 3838 0535

Email
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

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

City
Hamadan

Province
Hamadan

Postal code
38698-65178

Phone
+98 81 3838 0535

Email
ambehrad@yahoo.com

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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Email
ambehrad@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
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Amir Sadeghi
Position
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Email
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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