

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of program based on spiritual care on leukemia patients' hope and anxiety

Protocol summary

Patients' hope and anxiety

Study aim

Determining the effectiveness of the program based on spiritual care on leukemia patients' hope and anxiety

Design

The current study is a two-group randomized clinical trial that will be conducted with the participation of 100 patients. The research units will be selected by convenience sampling method and will be allocated into control and intervention groups by using randomization of the permutation block method.

Settings and conduct

The current study is a two-group randomized clinical trial that will be conducted with the participation of 100 leukemia patients in Hamadan. In the intervention group, the spiritual care program's group sessions are held in 4 sessions, 1 session per week for 45 to 60 minutes by the researcher. The topics of the meetings will include the evaluation of the spiritual needs of leukemia patients, religious care of leukemia patients, spiritual care-support of leukemia patients, and the evaluation of spiritual care. Completion of hope and anxiety questionnaires by patients will be done one month after the last care session. The control group will receive only usual medical care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of leukemia by a doctor, having at least reading and writing literacy, and the ability to communicate verbally. Exclusion criteria: unwillingness to participate in the study and the presence of other debilitating diseases.

Intervention groups

Intervention group: the group sessions of the spiritual care program will be held by the researcher for the intervention group during 4 sessions, 1 session per week for 45 to 60 minutes. After spiritual care intervention, patients' hope and anxiety will be assessed one month after the last care session. Control group: patients in the control group will receive only routine care.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N40**

Registration date: **2022-11-05, 1401/08/14**

Registration timing: **prospective**

Last update: **2022-11-05, 1401/08/14**

Update count: **0**

Registration date

2022-11-05, 1401/08/14

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of program based on spiritual care on leukemia patients' hope and anxiety

Public title

Effectiveness of a program based on spiritual care on hope and anxiety

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of leukemia according to the doctor Having at least reading and writing literacy Ability to communicate verbally

Exclusion criteria:

Unwillingness to participate in the study Presence of other debilitating diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, patients will be registered according to the determined sample size (100 people) and according to the entry criteria, and with the block method (the 2 block method is used, two letters A and B with different permutations in the block and randomly select 50 blocks and assign each block to 2 people) will be assigned to two groups.

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

Hamadan University of Medical Sciences, Shahid

Fahmideh Street

City

Hamadan

Province

Hamadan

Postal code

38698-65178

Approval date

2022-10-22, 1401/07/30

Ethics committee reference number

IR.UMSHA.REC.1401.624

Health conditions studied

1

Description of health condition studied

Leukemia

ICD-10 code

C95.90

ICD-10 code description

Leukemia, unspecified not having achieved remission

Primary outcomes

1

Description

Patients' hope

Timepoint

One month and two months after the intervention

Method of measurement

Snyder hope questionnaire

2

Description

Patients' anxiety

Timepoint

One month and two months after the intervention

Method of measurement

Beck anxiety questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, the group sessions of the spiritual care program will be held during 4 sessions, 1 session each week for 45 to 60 minutes by the researcher. Texts related to spiritual care have been localized by a group of experts in Iran's health system. Completing the patients' hope and anxiety questionnaires will be done one month and two months after the last care session.

Category

N/A

2

Description

Control group: The control group will receive only routine medical care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mohammad Torabi

Street address

Hamedan - the beginning of Eram Boulevard - Shahid Beheshti Hospital

City

Hamadan

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38698-65178

Phone

+98 918 316 0499

Email

mtorabi316@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokouhi

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street

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shokoohi@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Deputy of research and technology

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

Mohammad Torabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Latest degree

Ph.D.

Other areas of specialty/work

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

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Full name of responsible person

Mohammad Torabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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