Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

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
Patients' hope and anxiety

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
Province
Hamadan
Postal code
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
City
Hamadan
Province
Hamadan
Postal code
38698-65178
Phone
+98 81 3838 0535
Email
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
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
38698-65178
Phone
+98 81 3838 0535
Email
mtorabi316@gmail.com

Person responsible for scientific 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
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Street
City
Hamadan
Province
Hamadan
Postal code
38698-65178
Phone
+98 81 3838 0535

Email
mtorabi316@gmail.com

Person responsible for updating data

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

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Street

City
Hamadan

Province
Hamadan

Postal code
38698-65178

Phone
+98 81 3838 0535

Email
mtorabi316@gmail.com

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