Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of two visual and teach-back-based educational methods on leukemia patients' self-efficacy and quality of life

Protocol summary

Study aim

Comparison of the effect of two visual and teach-back-based educational methods on leukemia patients' self-efficacy and quality of life

Design

The present study is a three-group randomized clinical trial that will be conducted with the participation of 90 patients. The research units will be selected by the convenience sampling method and will be divided into three groups (one control and two intervention groups) by the randomization method of the permutation block of six.

Settings and conduct

The present study will be conducted in Shahid Beheshti Hospital in Hamedan on 90 leukemia patients in three groups (two intervention groups and one control group). In the two intervention groups, education will be taught in two teach-back-based and visual methods about leukemia, nutrition, and drugs.

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

In the first intervention group, a teach-back-training method regarding diet, physical activity, and how to take medications will be provided during eight weekly sessions, each session lasting 45-60 minutes. In the second intervention group: face-to-face training using boards and posters regarding diet, physical activity, and how to take medications will be provided in eight weekly sessions, each session lasting 45-60 minutes. In the control group: patients in the control group will receive only routine care.

Main outcome variables

patients' self-efficacy and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211227053551N3**
Registration date: **2022-11-26, 1401/09/05**
Registration timing: **prospective**

Last update: **2022-11-26, 1401/09/05**
Update count: **0**

Registration date

2022-11-26, 1401/09/05

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

2022-12-22, 1401/10/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of two visual and teach-back-based educational methods on leukemia patients' self-efficacy and quality of life

Public title
Comparison of the effect of two visual and teach-back-based educational methods on self-efficacy and quality of life
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of stroke 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: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method will be done using the permutation block method. So that 15 blocks of six contain three letters A, B, and C, each of which is repeated twice in each block, such as AABBCC, ABABCC, ACBBAC, etc will be produced and placed in envelopes. Then, when the patients enter the study, one of the envelopes will be randomly selected and the first six patients will be assigned to three groups according to the desired block. This process will continue until the total number of samples is completed.
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
2022-10-29, 1401/08/07
Ethics committee reference number
IR.UMSHA.REC.1401.656

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' self-efficacy
Timepoint
One month and two months after the intervention
Method of measurement
Sherer General Self-Efficacy Questionnaire

Secondary outcomes

1

Description
Patients' quality of life
Timepoint
One month and two months after the intervention
Method of measurement
Questionnaire of quality of life of cancer patients

Intervention groups

1

Description
Intervention group 1: Training will be implemented in a teach-back method. The educational content will be taught to the patients face-to-face by the researcher in simple language without using medical terms. Then the patient is asked to express the educational content in his language. If the patient does not understand the content correctly, the educational content will be taught to him again.
Category

Lifestyle

2

Description
Intervention group 2: Training will be done face-to-face with the use of simple pictures, posters, drug labels to remind the patients of taking their medications.
Category
Other

3

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
Seyyedeh Nayerh Fallahan
Street address
Hamedan - the beginning of Eram Boulevard - Shahid Beheshti Hospital
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nfalahan92@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Reza Shokouhi
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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
Iran University of Medical Sciences
Full name of responsible person
Seyyedeh Nayerh Fallahan
Position
instructor
Latest degree
Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

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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