

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 AABBC, 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

City

Hamadan

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38698-65178

Phone

+98 81 3838 0535

Email

nfalahan92@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

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 scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Position

instructor

Latest degree

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Other areas of specialty/work

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

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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