Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

The effect of a psycho-educational program on the sleep quality of patients with Leukemia

Protocol summary

Study aim

Determining the effect of a psycho-educational program on the sleep quality of patients with Leukemia

Design

The study groups included patients with different types of leukemia who are referred to the selected hospital of Isfahan University of Medical Sciences and have entry requirements. After convenient Sampling, samples as non random allocation are divided into two groups based on the even file number (intervention group) and odd file number (control group). The sample size is estimated to be 30 in each group. Clinical trial with a control group, with parallel groups, non randomized trial.

Settings and conduct

Place: Seyed al Shohada Hospital in Isfahan How to do: At first, the questionnaires are completed before the intervention. Then, the training sessions are held for both groups. After a month, the sleep quality questionnaire is completed again.

Participants/Inclusion and exclusion criteria

Entry requirements: age more than 18 years, definite leukemia diagnosis, ability to read and write, ability to attend training sessions, sign a written informed consent, least 6 months past to diagnose the disease, knowing the patient of illness. Conditions of no entry: other chronic diseases, end-stages of life, use of psychiatric drugs, admission to psychiatric wards

Intervention groups

Intervention group: 6 sessions. sessions topics: 1. definition of disease, 2. sleep disorders and hypnotic drugs, 3. stress and relaxation techniques, 4. pain control, 5. review of previous contents, 6. question and answer, and filling the questionnaire. Control group: a cancer education training session in the form of a pamphlet.

Main outcome variables

Quality of sleep in patients with leukemia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181006041249N1**
Registration date: **2018-12-18, 1397/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-18, 1397/09/27**
Update count: **0**

Registration date

2018-12-18, 1397/09/27

Registrant information

Name

faeze Ashenaye roudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5422 2075

Email address

faeze.ashena@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-22, 1397/07/30

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a psycho-educational program on the sleep quality of patients with Leukemia

Public title
The effect of a psycho-educational program on Leukemia
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Have more than 18 years of age; Diagnosis of leukemia is confirmed by an expert oncologist; Ability to communicate and have the physical and mental ability to attend training sessions and complete the questionnaire; Written informed consent to participate in the study; At least 6 months past from diagnosis; Patient aware of his or her illness; Ability to read and write.
Exclusion criteria:
Have other chronic diseases; The patient is in the final stages of life; Use of psychiatric drugs; Hospitalization in psychiatric departments.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
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 Isfahan University of Medical Sciences
Street address
Hezar jerib street، Dormitory of isfahan university
City
Esfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2018-01-08, 1396/10/18
Ethics committee reference number
IR.MUI.REC.1396.3.698

Health conditions studied

1

Description of health condition studied
Leukemia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sleep quality
Timepoint
At the beginning of the study, before the intervention and one month after the intervention
Method of measurement
Petersburg Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention consists of 5 one-hour sessions, once a week, and one 1-hour session, which is held one month later. Sessions are held individually or in groups of 12 to 8 people, depending on the sample participation. Contents are provided by PowerPoint and by the researcher. Training topics: 1. Definition of the disease 2. Sleep disturbances and hypnotic drugs 3. Stress and relaxation techniques 4. Pain control 5. Review of the contents of the previous sessions 6. Questions and Answers , Complete questionnaires.
Category
N/A

2

Description
Control group: Only receive a general cancer education session.
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Seyed Alshohada hospital in Isfahan

Full name of responsible person
Faeze Ashenaye Roudi

Street address
Motahari Street

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http://omid.mui.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjoye Javanmard

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Web page address
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Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Masoud Bahrami

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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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
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The data will be published after being unidentifiable through the article
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Only scholars working in academic institutions
Under which criteria data/document could be used
No other use is allowed
From where data/document is obtainable
Email to: faeze.ashena@nm.mui.ac.ir.
What processes are involved for a request to access data/document
The request will be sent to the registered email address sent after the data email is read.
Comments