

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 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

Isfahan

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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Isfahan

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8184917911

Phone

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Email

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Web page address

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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Phone

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Email

research@mui.ac.ir

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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Email

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Person responsible for scientific 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 updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Faeze Ashenaye Roudi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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