

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The effect of sleep education on the quality of sleep in cancer patients during chemotherapy

Protocol summary

Study aim

The effect of sleep health education on sleep quality in people with cancer during chemotherapy courses in Isfahan

Design

Clinical trials with control group, with parallel groups, randomized

Settings and conduct

The study was conducted in 1397_1398 in Isfahan. The target population of Cancer patients undergoing chemotherapy, referred to the Milad hospital and Alzahra clinic.

Participants/Inclusion and exclusion criteria

Willingness to participate in research Having at least 18 and up to 65 years of age Reading and writing skills getting Cancer and being on chemotherapy course, For whatever reason, They were reluctant to continue in the study If there is an unforeseen crisis or accident during the course of research for them Failure to attend at least one training session Questionnaires with at least 20% not completed are removed and replaced with other patients

Intervention groups

70 of these patients were selected by simple randomization method and then using SPSS software, 35 patients were randomly divided into two groups of intervention and 35 patients in control group. Sleep quality in both groups was assessed using the Pittsburgh Sleep Quality Index (PSQI). The researcher applied sleep education to the intervention group, after one and three weeks the quality of sleep was again assessed in both groups, and the results of the patients' sleep quality were compared before, one week and three weeks after the intervention. Intervention is conducted in 2 training sessions for 60 minutes using a lecture, group discussion, question and answer and educational pamphlets by a psychologist and a physician.

Main outcome variables

Sleep education, chemotherapy, sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190730044379N1**

Registration date: **2019-09-10, 1398/06/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-10, 1398/06/19**

Update count: **0**

Registration date

2019-09-10, 1398/06/19

Registrant information

Name

Ali Hajigholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3261 6654

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alihajigholami@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-06, 1398/05/15

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of sleep education on the quality of sleep in cancer patients during chemotherapy

Public title

The effect of sleep education on the quality of sleep in cancer patients during chemotherapy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in research Having at least 18 and up to 65 years of age Reading and writing skills getting Cancer and being on chemotherapy courses

Exclusion criteria:

For whatever reason, They were reluctant to continue in the study If there is an unforeseen crisis or accident during the course of research for them Failure to attend at least one training session Questionnaires with at least 20% not completed are removed and replaced with other patients

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

N/A

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

Isfahan University of Medical sciences, Hezar jareeb street, Isfahan, Iran

City

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Province

Isfahan

Postal code

8174675731

Approval date

2019-08-04, 1398/05/13

Ethics committee reference number

IR.MUI.MED.REC.1398.242

Health conditions studied

1

Description of health condition studied

cancer patients during chemotherapy

ICD-10 code

Z51.11

ICD-10 code description

Encounter for antineoplastic chemotherapy

Primary outcomes

1

Description

Sleep education

Timepoint

Beginning of study and 8 weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

2

Description

Percentage of people with a Pittsburgh questionnaire score above 1

Timepoint

Beginning of study

Method of measurement

Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The two 60 minute training sessions are conducted by a psychologist and a physician using lecture style, group discussion, question and answer and educational pamphlets.

Category

Rehabilitation

2

Description

Control group: There is no cure for this group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra clinic

Full name of responsible person

Dr.Ali Hajigholami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Dr.Ali Hajigholami

Position

Associated professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be accessible

When the data will become available and for how long

Immediately after the article was published

To whom data/document is available

To anyone who needs this information

Under which criteria data/document could be used

Email to Dr Haji gholami

Email:Ali_hajigholami@yahoo.com

From where data/document is obtainable

Dr Ali Hajigholami Email:ali_hajigholami@yahoo.com

What processes are involved for a request to access data/document

Email to Dr Ali Haji gholami

Comments