Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Email address
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
Isfahan
Province
Isfehan
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

Street address
Sheikh Mofid street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8164969479

Phone
+98 31 3663 1677

Email
ali_hajigholami@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr.Shaghayegh haghjoo javanmard

Street address
Medical school of Isfahan, deputy of research

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 8092

Fax
+98 31 3669 2174

Email
sh_haghjoo@med.mui.ac.ir

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 proffesor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology

Street address
Medical university,Alzahra hospital

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
0098 31 366855555

Fax
+98 31 3624 4221

Email
ali_hajigholami@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr.Ali Hajigholami

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology

Street address
alzahra hospital,Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
0098 31 366855555

Email
Ali_hajigholami@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr.Ali Hajigholami
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
Street address
Alzahra hospita,Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
0098 31 366855555
Email
ali_hajigholami@yahoo.com

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