

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Investigation the effect of guided imagery on anxiety and quality of sleep in cancer patients

Protocol summary

Study aim

The aim of this study will be to determine the effect of guided imagery compared with routine care on anxiety and quality of sleep among cancer patients

Design

Two arm parallel randomized controlled trial

Settings and conduct

70 Eligible patients with cancer who were referred to the chemotherapy department of Shahid Beheshti Hospitals affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. intervention group will listen to the guided imagery CD which is prepared by the researcher by using a CD player and headphones for 25 minutes, 2 times a week at night (between 20 and 21 pm) for 4 weeks, in addition to routine care.

Participants/Inclusion and exclusion criteria

Some items of inclusion criteria included: patients at the age of 18 to 70 years; having full consciousness and Not having hearing loss . Also, some exclusion criteria included: if the patients suffer from Severe physical disease or unable to collaborate.

Intervention groups

cancer patients will be assigned into intervention and control groups through Simple randomization method

Main outcome variables

The State-Trait Anxiety Inventory and Pittsburgh Sleep Quality Index will be quantified at study baseline, end-of-trial and 4 weeks after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180707040374N1**

Registration date: **2018-08-27, 1397/06/05**

Registration timing: **prospective**

Last update: **2018-08-27, 1397/06/05**

Update count: **0**

Registration date

2018-08-27, 1397/06/05

Registrant information

Name

mohammad afshar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

afshar_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-28, 1397/06/06

Expected recruitment end date

2018-09-28, 1397/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of guided imagery on anxiety and quality of sleep in cancer patients

Public title

The effect of guided imagery on anxiety and quality of sleep in cancer patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients' willingness to participate in clinical trials
Patients at the age of 18 to 70 years old Having full consciousness
Diagnosis of cancer by a specialist within the last 6 months
Not having hearing loss Absence of opium addiction history
Do not take hypnotics and anxiety drugs Having anxiety Having a sleep disorder

Exclusion criteria:

Suffer from a severe physical disease

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple random sampling method will be used. samples of this study will be divided into two intervention and control groups using the random number table.

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 Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, 5th kilometer of Qotb -e Ravandi Blvd, Kashan, Iran

City

Kashan

Province

Isfahan

Postal code

87135/1416

Approval date

2018-06-18, 1397/03/28

Ethics committee reference number

IR.KAUMS.NUHEMP.RES.1397.014

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

2

Description of health condition studied

Quality of sleep

ICD-10 code

G47

ICD-10 code description

Sleep disorders

Primary outcomes

1

Description

The State-Trait Anxiety

Timepoint

At the beginning of the study , end-of-trial and 4 weeks after intervention

Method of measurement

The State-Trait Anxiety Inventory

2

Description

Sleep Quality

Timepoint

At the beginning of the study , end-of-trial and 4 weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intervention group will listen to the guided imagery CD which is prepared by the researcher by using a CD player and headphones for 25 minutes, 2 times a week at night (between 20 and 21 pm) for 4 weeks, in addition to routine care.

Category

Other

2

Description

Control group: they will receive only routine care
Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mohammad Afshar

Street address

Chemotherapy unit, Shahid beheshti hospital,
Pezeshk Blvd, 5th of Qotb-e Ravandi, Kashan city, Iran

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Email

Afshar_m@kaums.ac.ir

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<http://beheshti.kaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Kashan University of Medical Sciences, 5th kilometer
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Email

hamidi.gholamali2@gmail.com

Web page address

<http://research.kaums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Afshar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kashan University of Medical Sciences

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no program for its release

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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