Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effectiveness of internet-based cognitive behavioral intervention on sleep quality and insomnia severity in cancer survivors

Protocol summary

Study aim
Determination of the effectiveness of internet-based psychological intervention on insomnia severity, sleep quality, and daytime sleepiness in cancer survivors.

Design
This study is a randomized clinical trial (using block randomization with varying block sizes) with a control group and parallel design conducted on 30 patients. The study is not blinded (open label), but the allocation sequence is concealed.

Settings and conduct
The study is conducted in research centers and hospitals affiliated with Shahid Beheshti University of Medical Sciences. After initial screening and obtaining informed consent, participants are randomly assigned to intervention and control groups. The intervention group gains access to a designed website to receive educational and therapeutic content (including videos, text, and exercises). Assessments are performed at pre-test, post-test, and follow-up stages.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Cancer survivors (18-60 years) at least 6 months post-treatment, diagnosed with insomnia, and having internet access. Exclusion criteria: Severe depression or anxiety, substance abuse, other sleep disorders (e.g., apnea), and acute physical or brain diseases.

Intervention groups
Group 1 (Intervention): Receiving the Internet-based Cognitive Behavioral Therapy (ICBT-I) package including sleep hygiene education, stimulus control, sleep restriction, and cognitive restructuring via a dedicated website. Group 2 (Control): Placed on a waiting list and receive no intervention during the study period (usual care).

Main outcome variables
Insomnia severity, Sleep quality, Daytime sleepiness.

General information

Reason for update

Acronym
ICBT-C

IRCT registration information
IRCT registration number: **IRCT20230807059073N1**
Registration date: **2025-12-28, 1404/10/07**
Registration timing: **prospective**

Last update: **2025-12-28, 1404/10/07**
Update count: **0**

Registration date
2025-12-28, 1404/10/07

Registrant information

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Name of organization / entity
Ahrar Institute of Technology and Higher Education

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2027-02-20, 1405/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of internet-based cognitive behavioral intervention on sleep quality and insomnia severity in cancer survivors

Public title
Measuring the effect of internet-based intervention on reducing insomnia symptoms in cancer survivors

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 60 years At least 6 months passed since the completion of cancer treatment Diagnosis of insomnia disorder based on DSM-5 criteria Ability to read and write Access to the Internet and ability to use a computer or smartphone Signing the informed consent form

Exclusion criteria:
Moderate to severe depression or anxiety (based on DASS score) Presence of other acute psychiatric disorders (based on SCID interview) History of substance abuse Untreated other sleep disorders (e.g., sleep apnea or restless leg syndrome) Major physical or brain diseases (e.g., Parkinson's or MS)

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are assigned to intervention and control groups using permuted block randomization with varying (random) block sizes (e.g., 2 and 4), generated by Random Allocation Software (RAS). Using varying block sizes ensures unpredictability and prevents selection bias. Allocation concealment is achieved using sequentially numbered, opaque, sealed envelopes.

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
The Medical Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
Cancer Research Center, Shohada Tajrish Hospital, Tajrish Sq, Tehran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2023-07-23, 1402/05/01

Ethics committee reference number
IR.SBMU.CRC.REC.1402.001

Health conditions studied

1

Description of health condition studied
Insomnia Disorder (in cancer survivors)

ICD-10 code
G47.0

ICD-10 code description
Disorders of initiating and maintaining sleep [insomnia]

Primary outcomes

1

Description
Insomnia Severity

Timepoint
At baseline (before intervention), immediately after intervention, and at the follow-up phase.

Method of measurement
Insomnia Severity Index (ISI) questionnaire

2

Description
Sleep Quality

Timepoint
At baseline (before intervention), immediately after intervention, and at the follow-up phase.

Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

3

Description
Daytime Sleepiness

Timepoint
At baseline (before intervention), immediately after intervention, and at the follow-up phase.

Method of measurement
Epworth Sleepiness Scale (ESS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group receives the Internet-based Cognitive Behavioral Therapy (ICBT-I) package. This intervention involves access to a dedicated website that provides educational content (videos, text), sleep hygiene education, stimulus control techniques, sleep restriction, and cognitive restructuring in a step-by-step format over a specified period.
Category
Behavior

2

Description
Control group: The control group is placed on a waiting list and receives no specific intervention during the study period (usual care). To adhere to ethical standards, the intervention package will be offered to this group after the completion of the study and follow-up assessments.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Cancer Research Center, Shohada-e Tajrish Hospital
Full name of responsible person
Mona Malekzadeh Moghani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Research Directorate, Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Tabnak St., Evin, Chamran Highway
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Grant name
Research Proposal Budget
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mona Malekzadeh Moghani
Position
Associate Professor
Latest degree
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Other areas of specialty/work
Radiotherapy Oncology
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Person responsible for scientific inquiries

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Position

Associate Professor

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Web page address

https://scholar.google.com/citations?user=V1LN5rkAAAAJ&hl=en

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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available