

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of effectiveness of sleep hygiene education on sleep quality of patients with breast cancer

Protocol summary

Study aim

Evaluation of effectiveness of sleep hygiene education on sleep quality of patients with breast cancer

Design

A clinical trial, randomized, non-blinded, with a control group, with a parallel design, for 74 patients who are randomly allocated in two intervention and control groups and will be followed for 30 days.

Settings and conduct

This study will be conducted in two referral hospitals of Babol University of Medical Sciences on patients with breast cancer who have undergone mastectomy and have self-reported impaired sleep quality. Patients are followed for one month. Randomization is performed using permutation blocks method and with blocks of size 4. In each block, an equal number of people are allocated to both groups. The order of placement of intervention and control groups in each block is determined by a statistician.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 65 years; Suffering from stage 3 breast cancer who have undergone mastectomy.
Exclusion criteria: Patients with serious psychiatric disorders, dementia or delirium; Illiteracy; Taking sedative drugs before entering the study.

Intervention groups

Intervention group: Virtual and face-to-face training on the principles of sleep hygiene and free psychiatric visits for one month. Control group: Free psychiatric visit for one month.

Main outcome variables

Sleep quality based on Pittsburgh Sleep Quality Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150630022991N16**

Registration date: **2023-08-21, 1402/05/30**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-21, 1402/05/30**

Update count: **0**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name

Sussan Moudi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 5683

Email address

sussan.mouodi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness of sleep hygiene education on sleep quality of patients with breast cancer

Public title

The effect of sleep hygiene education on patients with

breast cancer

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years Breast cancer in stage 3 who have undergone mastectomy Self-reported sleep disorder
Exclusion criteria:
Severe psychiatric disorders, dementia or delirium in patient Illiteracy Consumption of sedative drugs before participation in the study

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

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is conducted using permutation blocks method and with blocks of size 4. In each block, an equal number of people are assigned to both groups (intervention and control). The order of placement of intervention and control groups in each block is determined by a statistician.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In order to conceal the treatment process, envelopes with the same shape are prepared according to the number of participants. A three-digit code is written on each envelope. Whenever the intervention initiates, an envelope is opened for each participant with the order of which has been already specified. Type of treatment (intervention or control) has been written inside the envelope.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Ganjafrooz Avenue, Babol

City

Babol
Province
Mazandaran
Postal code
4136747176
Approval date
2022-02-02, 1400/11/13
Ethics committee reference number
IR.MUBABOL.REC.1400.266

Health conditions studied

1

Description of health condition studied

Sleep disorder

ICD-10 code

F51

ICD-10 code description

Sleep disorders not due to a substance or known physiological condition

Primary outcomes

1

Description

Sleep quality

Timepoint

At the beginning of the study (day zero) and one month after the intervention

Method of measurement

Using the Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Virtual and face-to-face education of sleep hygiene and free psychiatric visit for one month. Following points are taught to the patient: 1- To sleep at a certain time and wake up at a certain time every day. 2- If she is hungry, she should eat a light meal before going to bed. 3- Have a regular exercise program. 4- Have almost an hour of relaxation before going to bed. 5- Keep her bedroom cool. 6- The bedroom should be dark. 7- The bedroom should be quiet. 8- Do not exercise right before going to bed. 9- Do not eat in bed. 10- A specific place should be considered to sleep and it should only be used for sleeping. 11- If she is worried about something while sleeping, she should write it down and deal with it tomorrow morning. 12- People who have insomnia, it is better to avoid daytime sleep. 13- Don't keep looking at the clock when she has insomnia. 14- Reducing the use of devices with screens before going to bed. 15- Do not eat heavy meals before going to bed. 16- Do not use tea and coffee after 6 o'clock in the evening. 17- Don't

smoke if she can't sleep. 18- Do not use alcohol to help sleep. 19- Do not exercise in bed. 20- Don't talk on the phone in bed.

Category

Lifestyle

2**Description**

Control group: Free psychiatric visit for one month

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

The surgery department of Shahid Beheshti Hospital

Full name of responsible person

Novin Nikbakhsh

Street address

Shahid Ghassemi Street

City

Babol

Province

Mazandaran

Postal code

4716681451

Phone

+98 911 122 7003

Fax

+98 11 3225 1664

Email

novinsu@hotmail.com

Web page address

<https://beheshti.mubabol.ac.ir/>

2**Recruitment center****Name of recruitment center**

The surgery department of Ayatollah Rohani Hospital

Full name of responsible person

Novin Nikbakhsh

Street address

Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

4717641367

Phone

+98 11 3223 8300

Fax

+98 11 3223 8309

Email

novinsu@hotmail.com

Web page address

<https://rohani.mubabol.ac.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Mehdi Rajabnia

Street address

Babol University of Medical Sciences, Ganjafrooz Avenue, Babol

City

Babol

Province

Mazandaran

Postal code

4717641367

Phone

+98 11 3219 7667

Fax

+98 11 3219 7667

Email

ramazan69@yahoo.com

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

Yes

Title of funding source

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Sussan Moudi

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Babol University of Medical Sciences, Ganjafrooz Avenue

City

Babol

Province

Mazandaran
Postal code
4717641367
Phone
+98 11 3236 8823
Email
sussan.mouodi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Sussan Moudi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address
Babol University of Medical Sciences, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
4717641367
Phone
+98 11 3236 8823
Email
sussan.mouodi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Sussan Moudi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address

Babol University of Medical Sciences, Ganjafrooz Avenue

City
Babol
Province
Mazandaran
Postal code
4717641367
Phone
+98 11 3236 8823
Email
sussan.mouodi@gmail.com

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

Due to the limitations associated with the database of breast cancer patients, there is no plan to publish the data of these patients.

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

There is no program for sharing the research data.

When the data will become available and for how long

There is no program for sharing the research data.

To whom data/document is available

There is no program for sharing the research data.

Under which criteria data/document could be used

There is no program for sharing the research data.

From where data/document is obtainable

There is no program for sharing the research data.

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

There is no program for sharing the research data.

Comments