

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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