Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Examining the Effect of Benson's Relaxation Technique on sleep quality among women with Breast Cancer post mastectomy surgery

Protocol summary

Study aim

Determining the effect of Benson relaxation technique on sleep quality in women with breast cancer after mastectomy

Design

Randomized clinical trial has two groups of control and intervention that is performed on 72 patients. For randomization, permutation blocks designed by G-Power software were used.

Settings and conduct

The researcher will start sampling with the approval of the ethics committee of Sabzevar University of Medical Sciences and referring to the officials of Shahid Modarres Hospital in Kashmar. After obtaining informed written consent, the samples will enter the research. The control group will receive only the usual treatments, but the intervention group will receive the Benson relaxation technique in addition to the usual treatments. After two months, the sleep quality questionnaire will be completed by individuals again and the results will be evaluated between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 30 and 55 years - full consciousness - Sleep quality score between 5 to 21 -No other metastatic disease -No side effects related to chemotherapy -No specific physical complications associated with surgery -No severe mental disorders. -Do not use sedatives. Criteria for not entering: or serous discharge at the operation site -Accompanying metastatic diseases -Severe mental disorders and the use of sedatives - Patients who have undergone surgery before the last four months. -Known neurological andNeuromuscular disorders -Use other therapies while studying .

Intervention groups

The control group will perform only the usual treatments, but the intervention group will receive Benson's relaxation technique in addition to the usual treatments.

Main outcome variables

Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210108049964N1**
Registration date: **2021-02-06, 1399/11/18**
Registration timing: **prospective**

Last update: **2021-02-06, 1399/11/18**
Update count: **0**

Registration date

2021-02-06, 1399/11/18

Registrant information

Name

Iran Chabok

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5524 7435

Email address

chabokr9@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Examining the Effect of Benson's Relaxation Technique on sleep quality among women with Breast Cancer post mastectomy surgery

Public title
The effect of Benson relaxation technique on sleep quality in patients with mastectomy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral Mastectomy Ages 30 to 55 Willingness to participate in the study Have full consciousness Sleep quality score between 5 and 21 which is considered as poor sleep quality No other metastatic disease The patient has undergone all chemotherapy and radiation therapy after surgery and has been controlled for the relevant complications. No specific physical complications associated with surgery No severe mental disorders. Do not use sedatives
Exclusion criteria:
Occurrence of physical complications related to surgery such as hematoma or serous discharge at the operation site Accompanying metastatic diseases Severe mental disorders and the use of sedatives Patients who underwent surgery before the last four months. Known neurological disorders such as Parkinson's or multiple sclerosis at the doctor's discretion Neuromuscular disorders Use of other therapies while studying
Age
From **30 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method in this study is based on quadruple blocks that have been designed based on GPower software. Thus, nineteen quadruple blocks are formed and within each block, two people are considered as intervention persons and two people are considered as controls. The main goal of this method is balance. The number of participants in each group
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 Sabzevar University of Medical Sciences
Street address
Shahrake Tohid
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Approval date
2020-05-19, 1399/02/30
Ethics committee reference number
IR.MEDSAB.REC.1399.061

Health conditions studied

1

Description of health condition studied
Breast cancer patients undergoing mastectomy
ICD-10 code
N60
ICD-10 code description
Benign mammary dysplasia

Primary outcomes

1

Description
Percentage of people whose sleep quality score is between 5 and 21.
Timepoint
Measurement of sleep quality score at the beginning of the study (before the intervention) and two months after the start of the Benson relaxation technique
Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Intervention group includes 36 female patients with breast cancer undergoing mastectomy who, in addition to the usual treatments, perform the

Benson relaxation technique twice a day, in the morning and in the afternoon, each time for twenty minutes for two months. Performing the correct Benson relaxation technique This technique is performed in the following sequence. The patient is asked to lie down in a comfortable, quiet place and close his eyes, then gently relax his muscles from the bottom of the body upwards (first the leg muscles relax and then this relaxation continues to the face) and At the same time, slowly begin to breathe deeply, inhaling through the nose and exhaling through the mouth. The patient is asked to whisper number one in order to focus more on his breathing as he exhales. The person continues this position for five minutes and during this time all the muscles of the body are at rest The patient is then asked to open his eyes slowly, so that the body is motionless for a few minutes. It is important to note that one should not worry about deep relaxation. Rather, relaxation should be allowed to occur spontaneously, and if some negative thoughts cause a loss of focus for relaxation, people are asked to ignore these thoughts.

Category

Treatment - Other

2

Description

Control group: The control group includes 36 women with breast cancer who have undergone a unilateral mastectomy. The research units in this group perform only the usual pre-study treatments and are controlled for two months in terms of exclusion criteria, etc. They will be followed up and then the sleep quality questionnaire will be completed by them again

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Screening and Diagnosis Center of Shahid Modarres Hospital

Full name of responsible person

Dr Nahid Karimi

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Razi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Mohammadreza Ghasemi

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Grant name

Sabzevar University of Medical Sciences

Grant code / Reference number

99058

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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

Sabzevar University of Medical Sciences

Full name of responsible person

Raziyeh Chabok

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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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
Due to confidentiality and moral issues and the lack of necessity, there is no plan to publish them.
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