

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effects of Two Techniques of Anxiety Management for Mastectomy Candidates: Benson's Relaxation and Rhythmic Breathing

Protocol summary

Summary

The objective of this clinical trial is to compare the effects of Benson relaxation and rhythmic breathing on anxiety of patient candidates mastectomy. The study population will be women undergoing mastectomy in the Emam Khomeini hospital. Ninety participants were randomly assigned to of Benson relaxation and rhythmic breathing, or control groups. In the Benson Relaxation group after providing quiet environment will be taught this relaxation to the patient and she will be asked to follow 2 times relaxation for 20 minutes in the supine position with an 2-hours intervals. in Rhythmic breathing group after training, participants will be asked as well as Benson relaxation follow 2 times Rhythmic breathing for 20 minutes Sitting in a comfortable position With an 2-hours interval. The control group will not receive any type of intervention but only like two Intervention groups, cognitive and somatic anxiety questionnaire will be completed by the participants at first meeting, in the night of intervention, tomorrow morning and post-operative.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042017350N1**

Registration date: **2014-05-05, 1393/02/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-05-05, 1393/02/15

Registrant information

Name

Fatemeh Sadeghiyan

Name of organization / entity

Tehran University of Medical Sciences,nursing and midwifery university

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology Tehran university of Medical Science.Ghods street. Keshavarz blvd.Tehran.Iran

Expected recruitment start date

2014-04-22, 1393/02/02

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Two Tecniques of Anxiety Management for Mastectomy Candidates: Benson's Relaxation and Rhythmic Breathing

Public title

Impact of relaxation on anxiety resulting from breast surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: female gender; age 20 to 60 years old; no trouble hearing; lack of mental illness known; not taking anti-anxiety drugs; not suffering from substance

abuse; unfamiliarity with the same period of benson relaxation or rhythmic breathing in the intervention group; lack of musculoskeletal disorders; not suffering from respiratory disorders such as asthma; ability to communicate in Persian language. Exclusion criterion: not wanting to continue working in the research study at any time.

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Tehran University of Medical Sciences

Street address

Central building, Tehran University of Medical Sciences, Keshavarz blvd.

City

Tehran

Postal code

1417614411

Approval date

2013-05-25, 1392/03/04

Ethics committee reference number

92/130/341/3

Health conditions studied

1

Description of health condition studied

anxiety

ICD-10 code

F48.0

ICD-10 code description

anxiety:stat

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention, the night after intervention, tomorrow morning- after operation and after consciousness mastectomy surgery

Method of measurement

Cognitive Somatic Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

1-benson relaxation: the researcher to patient education that in the best situation in which to feel comfortable being in bed, close her eyes, then it is a word that always reminds him peace select, start breathing deep and regular, inspiration from mouth and expiration through the nose and during each exhale to repeat that's word. The tip of the toes, relax her muscles and continues this to upper body. Then twice with an interval of 2 hours each time, perform 10-20 minutes of benson relaxation.

Category

Prevention

2

Description

2-rhythmic breathing: patient sitting on a chair with closed eyes, neck and chest raised and puts her feet on the ground quite a stretch. then start to inspiration and expiration: in the inspiration the chest and abdomen fills of the air, after the deepest inspiration will be empty her chest. The same procedure is done with a focus on breathing in different positions. Then twice with an interval of 2 hours each time, perform 10-20 minutes of rhythmic breathing.

Category

Prevention

3

Description

3-control: receive routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital, Imam Khomeini Cancer Institute

Full name of responsible person

Dr. Zohreh Parsa Yekta, Associate of professor

Street address

Imam Khomeini hospital, End of Keshavarz Boulevard

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masood Yunesiyan

Street address

The Sixth Floor, Deputy of Research and Technology, Ghods street, Keshavarz blvd, Tehran

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Tehran

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Fatemeh Sadeghiyan Rizi

Position

Bachelor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty