

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 913 236 7544

##### Email address

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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

**City**

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

**City**

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**

Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Sadeghiyan Rizi

**Position**

Bachelor

**Other areas of specialty/work****Street address**

No. 67, Babajani Alley, Enghelab Street, Zarrin Shar, Isfahan

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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PhD

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<http://www.tums.ac.ir/faculties/?facultyID=642>

### Person responsible for updating data

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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*