

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of progressive muscle relaxation and Swedish massage on mood disorders in breast cancer patients undergoing radiotherapy

Protocol summary

Summary

This research is an experimental , randomize clinical trial study. Mainly aim of the study is to examine the impact of progressive muscle relaxation and Swedish massage on mood disorders in breast cancer patients undergoing radiotherapy .Sample size: 150 patients with breast cancer undergoing radiotherapy. Inclusion criteria: age 20-60 years; disease stage 1-3 breast cancer; Parsyal or total mastectomy; radiation treatment orders for treatment of breast cancer; no metastasis to other parts of the body; no history of mental illness or other illness chronic; non-use of drugs; muscle relaxants; hypnotics and psychotropic.The exclusion criteria is: participation in counseling and educational programs to coincide with the intervention; the use of psychotropic drugs and the presence of clinical signs and symptoms reported during the treatment of metastasized to other parts of the body; medical records; the diagnosis of infection by psychological doctor there stressful events (divorce, death of relatives, loss of job, etc.) within the last 6 months. Sampling starts on 10/03/93. All participants will respond to the questionnaire. The first group receive Swedish massage three times a week, each lasting 30 min during the 5 weeks. The second intervention group will be trained in muscle relaxation and give the CD to people who are asking these exercises at home for 30 minutes, once every day for 5 weeks. Control group will receive routin care of the center. After the session questionnaires were completed by patients. the outcome Study relieve or alleviate mood disorders with progressive muscle relaxation and Swedish massage techniques in breast cancer patients undergoing radiotherapy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312102751N11**

Registration date: **2014-06-10, 1393/03/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-10, 1393/03/20

Registrant information

Name

Masoomeh Kheirkhah

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8247 1000

Email address

kheirkhah@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-05-31, 1393/03/10

Expected recruitment end date

2014-11-01, 1393/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of progressive muscle relaxation and Swedish massage on mood disorders in breast cancer patients undergoing radiotherapy

Public title

Influence of progressive muscle relaxation and Swedish massage on mood disorders in breast cancer patients undergoing radiotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 20-60 years; disease stage 1-3 breast cancer; Parsyal or total mastectomy; radiation treatment orders for treatment of breast cancer; no metastasis to other parts of the body; no history of mental illness or other illness chronic; non-use of drugs; muscle relaxants; hypnotics and psychotropic. The exclusion criteria is: participation in counseling and educational programs to coincide with the intervention; the use of psychotropic drugs and the presence of clinical signs and symptoms reported during the treatment of metastasized to other parts of the body; medical records; the diagnosis of infection by psychological doctor there stressful events (divorce, death of relatives, loss of job, etc.) within the last 6 months.

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: **150**

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 Apartment Of Tehran University Of Medical Sciences, Keshavarz blvd

City

Tehran

Postal code**Approval date**

2014-05-19, 1393/02/29

Ethics committee reference number

403/130/93/5

Health conditions studied**1****Description of health condition studied**

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Anxiety

Timepoint

Before Intervention and After the intervention

Method of measurement

Affective Control Scale

2**Description**

Anger

Timepoint

Before Intervention and After the intervention

Method of measurement

Affective Control Scale

3**Description**

Depression

Timepoint

Before Intervention and After the intervention

Method of measurement

Affective Control Scale

4**Description**

pain

Timepoint

Before Intervention and After the intervention

Method of measurement

Affective Control Scale

5**Description**

Positive affect

Timepoint

Before Intervention and After the intervention

Method of measurement

Affective Control Scale

Secondary outcomes

empty

Intervention groups

1

Description

In progressive muscle relaxation group, these techniques during a session will be training and then give the CD to people who are asking these exercises at home for 30 minutes, once every day for 5 weeks

Category

Behavior

2

Description

in The massage group, receive Swedish massage three times a week, each lasting 30 min during the 5 weeks.

Category

Other

3

Description

Control group will receive routine care of the center.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute, Imam Khomeini Hospital, Tehran
University of Medical Sciences

Full name of responsible person

Sara darabpour

Street address

Dr gharib Street - Keshavarz Blvd - Imam Khomeini
Hospital

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Masood Younesian

Street address

Central Building of Tehran University of Medical
Sciences, The Qods Street, Keshavarz Blvd

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

School of Nursing and Midwifery Tehran University of
Medical Science

Full name of responsible person

Masoom Kheirkhah

Position

Ms Midwifery/Master of Science

Other areas of specialty/work

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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