Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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/د

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 routin 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
Masoome Kheirkhah
Position
Ms Midwifery/Master of Science
Other areas of specialty/work
Street address
Mirkhani street, Tohid square, Tehran
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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Other areas of specialty/work

Street address

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City

Tehran

Postal code

Phone

00

Fax

Email

Web page address

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