Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of the slow stroke back massage (SSBM) on ‘anxiety’ among older woman with breast cancer undergoing chemotherapy

Protocol summary

Summary

Objectives: The aim of this study is to determine the effect of slow stroke back massages (SSBM) on ‘anxiety’ among older woman patients with breast cancer undergoing chemotherapy. design: Experimental phase 2 clinical trial with a control group. Study population: Elderly women patients with breast cancer underwent chemotherapy regimens, those who admited to oncology ward of Firouzgar and Hazrate Rasoul Hospitals. Main inclusion criteria: Those who have no cognitive impairment regarding to AMT. Those who have at least 60 years of age or older. Those who received at least one chemotherapy session before the intervention.Those who have breast cancer in stages I, II and III. Main exclusion criteria: Those who Disaffiliate or death. Those who taking anti-anxiety drugs, anticoagulants, corticosteroids and narcotics. Those who Discharge before three days of admission due to the chemotheapy. Sample size: 84 Main outcome measures: Anxiety Intervention method: After fulfilment pre-tests (filling the demographic data form and geriatric anxiety scale (GAS)), the study group will be undergo slow strocke back massage for three consecutive days and for about 15 min per day that performed by a massage therapy licensed nurse. At the end of third day intervention, all participants completed the Geriatric Anxiety Scale (GAS) again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082223713N1**
Registration date: **2015-10-14, 1394/07/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-10-14, 1394/07/22

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the slow stroke back massage (SSBM) on ‘anxiety’ among older woman with breast cancer undergoing chemotherapy

Public title

Effect of massage therapy on anxiety among patients with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Those who have no cognitive impairment regarding to AMT; Those who have at least 60 years of age or older; Those who received at least one chemotherapy session before the intervention; Those who have no severe respiratory secretions caused by lung diseases; Those who not taking anti-anxiety drugs, Anticoagulants, corticosteroids and narcotics; Those who have breast cancer in stages I, II and III; Those who have no speech and hearing problem so that the data collection forms could be clearly filled in through face to face talks with the patient or on the telephone; Those who have no bed rest; Those who have no complications of skin and bone in the neck, back and sacrum; Those who have no spinal tumors. Exclusion criteria: Those who Disaffiliate or death; Those who taking anti-anxiety drugs, anticoagulants, corticosteroids and narcotics; Those who change their treatment from chemotherapy to Hormone Therapy and cytostatics; Those who Discharge before three days of admission due to the chemotheapy.

Age
From **60 years** old to **80 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study, sampling will be carried out using sequential (targeted) method. So that the patients those who have the inclusion criterias, will dispart into the intervention and control groups randomly by utlizing coin toss method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of the Iran University of Medical Science

Street address
Between the intersection of sheikh fazlolahe nouri st. and shahid chamran st., Toward the west of Shahid Hemmat Highway, Iran University of Medical Science, Tehran, Iran

City
Tehran

Postal code

Approval date
2015-07-20, 1394/04/29

Ethics committee reference number
IR.IUMS.REC.1394.9211580204

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 and immediately after of intervation

Method of measurement
Geriatric Anxiety Scale (GAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Applying slow Stroke Back Massage (SSBM) for three 15'' sessions in three consecutive days

Category
Other

2

Description
Control group: Does not receive any specific intervention

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrate Rasoul educational-medical center related to IUMS

Full name of responsible person
Massumeh Basiri

Street address
Hazrate Rasoul educational-medical center, At the corner of the Mansouri St, Niayesh St, Sattarkhan district, Urban area 2, Tehran, Iran
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2

Recruitment center
Name of recruitment center
Firouzgar educational-medical center related to IUMS
Full name of responsible person
Massumeh Basiri
Street address
Firouzgar educational-medical center, Karimkhan zand St. to Beh-Afarin St., Vali Asr Square, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Research- Iran University of Medical Science
Full name of responsible person
Dr Seyed Ali Javad Mousavi
Street address
The fifth floor of headquarters,Iran University of Medical Science, Between the intersection of sheikh fazlolahe nouri st. and shahid chamran st., Toward the west of Shahid Hemmat Highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Research- Iran University of Medical Science
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

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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