Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Studying the effect of strain counterstrain therapy on shoulder pain and range of motion in People with breast cancer after mastectomy surgery with chronic active trigger point pain

Protocol summary

Study aim

The purpose is to investigate the effect of strain counterstrain treatment on pain, pressure pain threshold, shoulder range of motion, shoulder pain and disability index, and quality of life questionnaire in people with cancer after mastectomy with chronic active trigger point pain. If the hypotheses are confirmed, this method can be used as one of the effective treatment methods available in the treatment of this group of patients.

Design

Clinical trial with control group, parallel groups, randomized, on 38 patients, coins were used for randomization .

Settings and conduct

38 patients are entered in accordance with the study conditions, they are initially evaluated in patient centers, and after receiving 12 intervention sessions, the final evaluation is done at the end of the 12th session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 35-65 years At least 6 months have passed since adjuvant treatment Having an active trigger point in at least two of the studied muscles The presence of pain in the upper limb Having pain 7-3 Exclusion criteria: Patients or return of breast cancer Bilateral mastectomy People with fibromyalgia Degenerative diseases of spine Taking anti-inflammatory medication in the last week Symptoms of upper extremity neuropathy People with depression People with lymphedema grade two and above Not wanting to participate in study

Intervention groups

Intervention group: in this group, in addition to the methods in the control group, since first session the strain counterstrain method will be used for the number of 5 more active trigger points in people. Control group: In the control group of subjects, after entering the study, people will be taught exercises and people will do the exercises.

Main outcome variables

pain intensity Pressure pain threshold range of motion Shoulder Pain and Disability Index Cancer Quality of Life Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231107059979N1**
Registration date: **2023-12-09, 1402/09/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-09, 1402/09/18**
Update count: **0**

Registration date

2023-12-09, 1402/09/18

Registrant information

Name

Fatemeh Dehghan sanij

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-08, 1402/09/17

Expected recruitment end date

2024-05-27, 1403/03/07

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the effect of strain counterstrain therapy on shoulder pain and range of motion in People with breast cancer after mastectomy surgery with chronic active trigger point pain

Public title
Effect of strain counterstrain treatment on shoulder pain and range of motion
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age range 35-65 years At least 6 months have passed from adjuvant treatment (chemotherapy and radiation therapy) after mastectomy Having an active trigger point in at least two muscles from the subscapularis, pectoralis major, infraspinatus and upper trapezius muscles The presence of pain in the upper limb region according to the diffusion pattern of muscle trigger point pain Pain score 7-3
Exclusion criteria:
Patients or return of breast cancer Bilateral mastectomy People with fibromyalgia Degenerative diseases of the spine Taking pain reliever, anti-inflammatory, muscle relaxant medicine in the last week Signs and symptoms of upper extremity neuropathy People with depression who receive medication and treatment for this issue People with lymphedema grade two and above Not willing to participate in the study or wanting to leave the study
Age
From **35 years** old to **65 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization (two patients who are very similar in terms of age, scar area, pain intensity, and body mass index are assigned to one of the control and test groups by tossing a coin.)
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o
Street address
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1473144113
Approval date
2023-11-05, 1402/08/14
Ethics committee reference number
IR.TUMS.FNM.REC.1402.155

Health conditions studied

1

Description of health condition studied
unilateral mastectomy
ICD-10 code
Z90.1
ICD-10 code description
Acquired absence of breast and nipple

Primary outcomes

1

Description
Pain intensity: It is a tool that determines the intensity of pain.
Timepoint
The beginning of the study (before the start of the intervention) - the last session (the twelfth session after the intervention)
Method of measurement
Visual analog scale: the person places a vertical mark on a continuous 100 mm line segment to indicate the intensity of pain, this line starts with the number 0, which indicates the absence of pain and discomfort, and the number 10, which indicates the worst pain that the person Ever experienced ends. In this study, the person reports the intensity of spontaneous pain, pain during active movement and pain with constant pressure applied by a pressure algometer in the upper limb area.

2

Description

Pressure Pain Threshold: The amount of direct pressure required to elicit a pain response in the target area.

Timepoint

The beginning of the study (before the start of the intervention) - the last session (the twelfth session after the intervention)

Method of measurement

Pressure pain threshold: after determining the active trigger point in the studied muscles (subscapularis, pectoralis major, infraspinatus and upper trapezius), the pressure algometer device is used to measure the pressure pain threshold of the active trigger point. The study subjects are asked to inform the pain threshold, after measuring 3 times, the average value is recorded as the pressure pain threshold.

Secondary outcomes

1

Description

Range of motion (ROM): The range of motion that occurs at a joint or set of joints.

Timepoint

The beginning of the study (before the start of the intervention) - the last session (the twelfth session after the intervention)

Method of measurement

In this study, passive range of motion of the shoulder is measured by a goniometer (standard, Saehan brand, large size).

2

Description

Shoulder Pain and Disability Index (SPDI): shoulder pain and disability index questionnaire, which aims to assess shoulder pain and disability and is filled by the individual.

Timepoint

The beginning of the study (before the start of the intervention) - the last session (the twelfth session after the intervention)

Method of measurement

This questionnaire has two dimensions, one is pain (5 questions) and the other is functional activities (8 questions) and the scoring of this questionnaire is based on a spectrum of 10 options, the score of each option is the same as the selected number, and finally the individual score is a number between zero and 130 and a larger number indicates greater disability.

3

Description

European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30): This questionnaire is used to measure the quality of life in cancer patients.

Timepoint

The beginning of the study (before the start of the intervention) - the last session (the twelfth session after the intervention)

Method of measurement

This questionnaire has 30 questions in 5 functional scales including: physical (5 questions), role playing (2 questions), emotional (2 questions), cognitive (4 questions), social (2 questions) and 9 symptom domains (fatigue, nausea and vomiting, pain, shortness of breath, sleep disorder, loss of appetite, constipation, diarrhea and financial problems) and evaluates the overall quality of life.

Intervention groups

1

Description

Intervention group: In this group, in addition to the methods in the control group from the first session the strain counterstrain method will be used for the 5 more active trigger points in people. Strain counterstrain method: In this method, the trigger point is identified by touch, and the therapist increases the pressure while still touching it so that the patient reports the onset of pain. Then passively put the muscle in a comfortable (shortened) position to reduce 70% of the pain and maintain a gentle touch on the trigger point, after 90 seconds the release is done and the therapist opens the patient to the resting position. This intervention will be repeated twice for each trigger point.

Category

Rehabilitation

2

Description

Control group: In the control group of subjects, after entering the study, people will be taught exercises and people will do the exercises. Start the exercises with 5 minutes of walking, then perform active stretching of the neck and upper trunk, flexion and extension (two repetitions of 20 seconds), perform active movement of the cervical spine for flexion, extension, and rotation (one set and ten repetitions). Performing active movement of the upper limbs for flexion, extension, abduction and adduction of the shoulder (two sets and ten repetitions) and finally performing relaxation exercises with deep breathing for 5 minutes (total duration of the exercises is 25 minutes).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Azimi Nejadan's office

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Fatemeh Dehghan Sanij

Position
Physiotherapist

Latest degree
Bachelor

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Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
هنوز تصمیم نگرفته‌ام - برنامه انتشار آن هنوز مشخص نیست
When the data will become available and for how long
هنوز تصمیم نگرفته‌ام - برنامه انتشار آن هنوز مشخص نیست
To whom data/document is available
هنوز تصمیم نگرفته‌ام - برنامه انتشار آن هنوز مشخص نیست
Under which criteria data/document could be used
هنوز تصمیم نگرفته‌ام - برنامه انتشار آن هنوز مشخص نیست
From where data/document is obtainable
هنوز تصمیم نگرفته‌ام - برنامه انتشار آن هنوز مشخص نیست
What processes are involved for a request to access data/document
هنوز تصمیم نگرفته‌ام - برنامه انتشار آن هنوز مشخص نیست
Comments