Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of Swedish massage on pain syndrome, shoulder function and quality of life in women undergoing mastectomy referred to Kerman oncology centers in 2022

Protocol summary

Study aim
Investigating The effect of Swedish massage on pain syndrome, shoulder function and quality of life in women undergoing mastectomy

Design
The clinical trial has a control group and a sham group without blinding on 60 randomized patients.

Settings and conduct
The Swedish massage intervention will be performed by a trained nurse at Javad Al-Aameh Clinic and doctors' office in two intervention and sham groups without blinding for three weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: no stressful event in the last 6 months, no use of anticoagulants, no massage contraindications, no substance abuse. Exclusion criteria: absence of more than two consecutive sessions

Intervention groups
The intervention group includes patients with breast cancer undergoing mastectomy who receive Swedish massage intervention. The sham group includes breast cancer patients undergoing mastectomy who receive surface touch intervention.

Main outcome variables
Shoulder pain, quality of life, shoulder function, Swedish massage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221213056803N1**
Registration date: **2023-01-08, 1401/10/18**
Registration timing: **prospective**

Last update: **2023-01-08, 1401/10/18**
Update count: **0**

Registration date
2023-01-08, 1401/10/18

Registrant information

Name
Zahra Rostami

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 34 3322 9141

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-01-21, 1401/11/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Swedish massage on pain syndrome, shoulder function and quality of life in women undergoing mastectomy referred to Kerman oncology centers in 2022

Public title
The effect of Swedish massage in women undergoing mastectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having breast cancer without metastases to other areas patients who have had one month of mastectomy surgery the absence of stressful events in the past 6 months the absence of using Painkillers, antiemetics or steroids no contraindications to massage

Exclusion criteria:

Absence of more than two consecutive sessions of intervention any severe physical disability that prevents the patient from participating in treatment sessions

Age

From **23 years** old to **63 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization type: block, Block size: 4 pieces, Randomization Unit: Individual, Randomization tool: R software, Concealment: Using sealed opaque envelopes, How people enter the random chain: People enter the random chain in the order of entering the study

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

Ethics Committee of Kerman University of Medical Science

Street address

Kerman, University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2022-11-22, 1401/09/01

Ethics committee reference number

IR.KMU.REC.1401.378

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

Disorders

ICD-10 code description

Disorders of breast(N60-N64)

Primary outcomes

1

Description

The score obtained from the quality of life European Organization for Research and Treatment of Cancer_EORCTquestionnaire

Timepoint

The effect of Swedish massage is measured three times before, immediately and one month after the intervention.

Method of measurement

The quality of life European Organization for Research and Treatment of Cancer_EORCTquestionnaire

2

Description

The score obtained from the shoulder function evaluation scale (shoulder disability) Shoulder Pain and Disability Index

Timepoint

The effect of Swedish massage is measured three times before, immediately and one month after the intervention.

Method of measurement

The shoulder function evaluation scale (shoulder disability) Shoulder Pain and Disability Index

3

Description

The score obtained from the shoulder function evaluation scale (pain) Shoulder Pain and Disability Index

Timepoint

The effect of Swedish massage is measured three times before, immediately and one month after the intervention.

Method of measurement

The shoulder function evaluation scale (Pain) Shoulder Pain and Disability Index

Secondary outcomes

empty

Intervention groups

1

Description
Patients in the intervention group will be treated for 3 weeks, 2 sessions a Week and 20 minutes each time from 14:00 to 17:00.
Category
N/A

2

Description
Control group: Sham group patients will be placed in the clinic for 3 Weeks, 2 sessions a week and 20 minutes each shift from 2:00 PM to 5:00 PM.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Javad Al-Aameh Clinic and Doctors Office
Full name of responsible person
Mohammad Hossein Pour Ebrahimi
Street address
No. 25, Abuzarshomali St., Kerman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
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Web page address
Grant name
Grant
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Kerman University of Medical Sciences
Full name of responsible person
Zahra Rostami
Position
Nurse
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Only part of the information, such as the main outcome, is shared.
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Academic and scientific institutions
Under which criteria data/document could be used
It is allowed to use in order to expand the science of complementary medicine. The condition for sending the application is to have a university affiliation.
From where data/document is obtainable
Email to the corresponding author, Dr. Meh Lagha Dehghan. Address: Nursing Research Center, Razi School of Nursing and Midwifery, Kerman University of Medical Sciences, Iran. Email: m_dehghan86@yahoo.com
What processes are involved for a request to access data/document
After checking the affiliation and the request via email sent to the responsible author and confirming the affiliation, the information will be provided to the researchers via email after one week.
Comments