

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 34 3322 9141

Email address

z.rostami@kmu.ac.ir

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

IR.KMU.REC.1401.378

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

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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7617763811

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhti

Street address

The beginning of Haft Bagh, Kerman University of Medical Sciences

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Fax

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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

Nursery

Street address

No. 8, Sedaghat Alley., No 7, vali asr Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mahlagha Dehghan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

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Email

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