Clinical Trial Protocol
Iranian Registry of Clinical Trials
28 Nov 2022

The effect of mirror therapy on shoulder pain and disability, quality of life and self-efficacy symptom management in unilateral mastectomy patients

Protocol summary

Study aim
The effect of mirror therapy on shoulder pain and disability, quality of life and self-efficacy symptom management in unilateral mastectomy patients

Design
A randomized, sham controlled clinical trial with a parallel group design of 35 patients in each arm enrolled by permuted block randomization

Settings and conduct
This study will be done in Shahid Motahari center in Shiraz. Eligible participants (70) will be allocated to intervention (35) or control (35) groups. Intervention group will do the mirror therapy with a set of exercises. Control group will do the same exercises without the mirror. Outcomes will be measured at the beginning, 3 weeks and 3 month later. Blinding is not possible for patients and researcher.

Participants/inclusion and exclusion criteria
Inclusion criteria: women with first time unilateral mastectomy; between 18-65 years old; at least 3 months has passed after their cancer treatment; complain about shoulder pain and disability in their affected side.
Exclusion criteria: Women with metastasis to other organs; having infectious diseases; disability to do voluntary upper limb movements; reconstructed breast surgeries; visual impairment; orthopedic issues; concentration problems; cognitive impairment

Intervention groups
Intervention group: Patients in this group do mirror therapy every day for 30 minutes, 5 days a week for 3 consecutive weeks. They must sit in front of a table with a mirror placed in their midsagittal plane while their affected limb faces the non-reflected side of the mirror and will do a set of exercises with their healthy hand and shoulder while watching the action reflection in the mirror. The control group will do the same exercises and the same time period without the mirror.

Main outcome variables
Breast cancer patients quality of life; Shoulder Pain and Disability Index; Symptom Managements Self-Efficacy in Breast Cancer.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: IRCT20200421047161N1
Registration date: 2020-08-01, 1399/05/11
Registration timing: registered_while_recruiting

Last update: 2020-08-01, 1399/05/11
Update count: 0
Registration date
2020-08-01, 1399/05/11

Registrant information
Name
Omsalimeh Roudi Rashtabadi
Name of organization / entity
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Iran (Islamic Republic of)
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Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-15, 1399/04/25
Expected recruitment end date
2020-11-15, 1399/08/25
Actual recruitment start date
Actual recruitment end date: empty
Trial completion date: empty

Scientific title:
The effect of mirror therapy on shoulder pain and disability, quality of life and self-efficacy symptom management in unilateral mastectomy patients

Public title:
The effect of mirror therapy in unilateral mastectomy patients

Purpose:
Supportive

Inclusion/Exclusion criteria:

**Inclusion criteria:**
- women who did unilateral mastectomy for the first time
- At least 3 month passed from completing cancer treatments
- Those who Complain of shoulder’s pain and disability after cancer treatments
- Age between 18 and 65 years old
- Women who do not participate in rehabilitation and exercise program simultaneous with intervention
- Women who are not prohibited to do physical activities
- Women who can read, write and continue exercises

**Exclusion criteria:**
- Those who have metastasis to other organs
- Those who have infectious diseases
- Those who are disable to do voluntary upper extremities movements
- Doing reconstructed breast surgeries
- Having vision problems
- Having orthopedic problems
- Having concentration problems
- Having cognitive problems

Age:
From 18 years old to 65 years old

Gender:
Female

Phase:
N/A

Groups that have been masked:
No information

Sample size:
Target sample size: 70

Randomization (investigator's opinion):
Randomized

Randomization description:
According to random sequences provided by random allocation software, random blocks are made and accordingly, patients randomly assigned to intervention or control group. The size of each block has determined by the statistician and is a multiple of number of groups (eg: for 2 treatment groups each block size is 4 ). Patients assignment to intervention and control group is not blinded for the patients and the researcher. Blinding is only possible for the person gathers data of stage 2 & 3 questionnaires and the statistician. They are not aware of the people assigned to intervention or control group.

Blinding (investigator's opinion):
Not blinded

Blinding description:
Placebo

Assignment:
Parallel

Secondary Ids:
empty

Ethics committees:
1

Ethics committee:
Name of ethics committee:
Ethics committee of Kerman University of Medical Sciences
Street address:
No. 2, Ibn Sina Street, Deputy of research and technology Bldg.
City:
Kerman
Province:
Kerman
Postal code:
7616913555
Approval date:
2020-06-02, 1399/03/13
Ethics committee reference number:
IR.KMU.REC.1399.174

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:
Shoulder Pain and Disability

Timepoint:
At the point of recruitment day, 3 weeks and 3 month later

Method of measurement:
shoulder pain and disability index

2

Description:
Quality of life of Breast Cancer Patients

Timepoint:
At the point of recruitment day, and 3 month later

Method of measurement:
Quality of life questionnaire - breast cancer 23 and quality
Description
Symptom management self-efficacy

Timepoint
At the point of recruitment day, 3 weeks and 3 months later

Method of measurement
Symptom management self-efficacy scale for breast cancer related to chemotherapy (SMSES-BC)

Secondary outcomes
empty

Intervention groups

1
Description
Intervention group: The study protocol includes: Using a three-week period of mirror therapy for unilateral mastectomy women. During these three weeks, women should sit on a comfortable chair in front of a table, which a stable mirror (50cm*50cm) is put in midsagittal part of her upper limb for 5 days a week, each day for 30 minutes in a duration of 3 weeks. She puts her healthy hand in front of the mirror and her affected hand in the back of the mirror. She begins with looking at her healthy hand for 5 minutes. Then for the rest of the 25 minutes she should move a towel to different directions on the surface. Then she should move her hand and shoulder up, down and to the sides with addition of putting wooden bricks on top of each other with her healthy hand. She must try to imagine that the action reflected in the mirror is actually the movement made by her disabled limb. All participants will receive a training video on their cell phones, a log book to report their training session and exercise guide images. After three weeks, there is no need for further exercises.

Category
Rehabilitation

Recruitment centers

1
Recruitment center
Name of recruitment center
Shahid Motahari Specialty and Subspecialty Complex

Full name of responsible person
Sanaz Roustaee

Street address
Shahid Motahari Specialty and Subspecialty Complex, next to Namazi Hospital, Namazi Square, Shiraz

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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
Kerman University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
just watching the healthy hand during exercises. After three weeks, there is no need for further exercises.
Person responsible for general inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Omsalimeh Roudi rashtabadi
Position
Assistant Professor
Latest degree
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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be 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
Not applicable