Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of pilates exercise on memory, attention and balance in woman with post mastectomy lymphedema, shahid motahari clinic

Protocol summary

Study aim
The effect of Pilates exercises on memory, attention and balance in women with lymphatic drainage after mastectomy.

Design
This is an interventional randomized clinical trial with parallel control and control group

Settings and conduct
The research area is Shahid Motahari Clinic in Shiraz. Samples are selected based on the conditions of entry into the study and written consent is taken from patients. Then, as a pre-test, Stroop tests for measuring attention, N-Back are used to measure memory and stand on one foot to measure the balance. In order to create the equilibrium of the samples, randomly and using a random number table, the blocks are assigned to the intervention and control groups by block method.

Participants/Inclusion and exclusion criteria
Conditions for the entry of women with secondary lymph nodes in the upper limb after mastectomy confirmed by the clinician and determined to participate in the study. Conditions of non-arrival of unwillingness to cooperate and creating any condition that leads to exacerbation of illness.

Intervention groups
The score of people's memory will be estimated through the N-Back test. The score will be estimated by the Stroop test. The score is the balance of scores that will be obtained by testing the single-leg stand. Pilates is a 4-week Pilates training session, with 3 hours per week per week. The exercises include general heating 10 minutes, specialized heating, prerequisite and level two pilates for 45 minutes and cooling the body for 5 minutes.

Main outcome variables
Independent variable Pilates exercises. Attention, memory, and variable equilibrium are dependent. Gender, age, other illnesses, drug use, time and volume of exercise, special motor control experiences are variable. The family environment, environment and living conditions are disturbing variables.

General information

Reason for update

Acronym
MBRCP

IRCT registration information
IRCT registration number: **IRCT20180511039615N1**
Registration date: **2019-09-02, 1398/06/11**
Registration timing: **retrospective**

Last update: **2019-09-02, 1398/06/11**
Update count: **0**

Registration date
2019-09-02, 1398/06/11

Registrant information

Name
Arezoo Kazemi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-16, 1398/02/26

Expected recruitment end date
2019-06-16, 1398/03/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of pilates exercise on memory, attention and balance in woman with post mastectomy lymphedema, shahid motahari clinic

Public title
The effect of pilates exercise in woman with breast cancer

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
The desire to participate in the research Having the ability to communicate verbally Women with secondary upper limb edema following mastectomy Ability to move independently At least one year of mastectomy surgery
Exclusion criteria:
Unwillingness to cooperate Exacerbation of illness or hospitalization Congestive heart failure or chronic obstructive pulmonary disease Patients under chemotherapy or radiation therapy Having a pacemaker heart Pregnancy

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
For sampling in this study, women with secondary lymphatic encephalomy following a modified radical mastectomy referring to the lymphatic clinic of Shahid Motahari clinic in Shiraz were selected based on their inclusion criteria and the purpose of the study. Then they were randomly selected Using random numbers, blocks are assigned to two groups by block method. First, the researcher creates the different permutations of A (representing the intervention group) and B (representing the control group), which consists of 6 different modes. For example, BABA-6, ..., ABAB-2, AABB-1). Then, to select the sample individuals from the table, move your finger randomly from a random point table in the direction of a row or column. If the number is between one and six, the permutation of that number is noted. For example, if the number 6 comes, we will record ABAB permutations, and thus eligible patients will be in the control group and in the intervention group (Pilates training group).

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 Shiraz University.

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Unit 52, Ava Building, Alleyway No. 27, Mali Abad Street

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shiraz

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7178644266

Approval date
2019-05-14, 1398/02/24

Ethics committee reference number
IR.SUMS.REHAB.REC.1398.015

Health conditions studied

1

Description of health condition studied
The effect of Pilates exercises on memory, attention and balance of women suffering from lumbar edema after mastectomy at Shahid Motahari Clinic

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Measuring patient balance

Timepoint
The patient's balance is measured one week before the start of the workout and one week after the exercise.

Method of measurement
This research is intended to measure the balance of scores obtained by a single-leg stand test.

2

Description
Measure the attention of patients

Timepoint
The time to measure patients' attention is one week before the beginning of the workout and one week after the workout.

Method of measurement

The score will be estimated by the Stroop test.

3

Description
Measuring patient memory
Timepoint
The time to measure patients' memory is one week before the start of the workout and one week after the workout.
Method of measurement
The score of people's memory will be estimated through the N-Back test.

Secondary outcomes

empty

Intervention groups

1

Description
This study included a control group and an intervention group. The intervention in this study is Pilates exercise for 4 weeks, 3 sessions for the intervention group for one hour in the training room and under the supervision of trained person. According to this protocol, the training consists of two blocks per day, with each block consisting of 3 exercises of dedicated warm-up, prerequisite and level two pilates. Pilates respiratory exercises have also been selected in these exercises with regard to their role in chest expansion, maximizing the range of neck, shoulder, elbow movements, ultimately maximizing elongation in the skin and activating the muscles around the armpit and lymph nodes. . Balanced exercises have also been selected to raise the balance of these individuals. In the present study, in order to get acquainted with the fellow patients in the educational intervention group, the benefits of Pilates exercises are presented on the entire body structure. It should be noted that besides the intervention described, both intervention and control groups will use standard deactivation treatment according to the clinical guidelines. After 2 weeks of Pilates training, we reach the T1 point in which we will remeasure the attention , Memory and balance for the participants in the intervention and control group and the patient's treatment process continues for 2 weeks, as in the past (from the start of the study in the same groups). At the end of the fourth week, from the moment of entering the study, the samples reach the T2 point, at which time the patient's attention, memory and balance will be measured again as a post-test. In the final stage, the data set will be analyzed by statistical tests. Considering the use of Pilates as a therapeutic and rehabilitation method in this study, the collaboration of Pilates specialists will be used to confirm the validity of the movements
Category
Rehabilitation

2

Description
Control group: In this research control group does not do any exercise. And they only do pre-tests and post-tests of memory, balance and attention tests. It should be noted that besides the intervention described, both intervention and control groups will use standard deactivation treatment according to the clinical guidelines. After 2 weeks of Pilates training, we reach the T1 point in which we will remeasure the attention , Memory and balance for the participants in the intervention and control group and the patient's treatment process continues for 2 weeks, as in the past (from the start of the study in the same groups). At the end of the fourth week, from the moment of entering the study, the samples reach the T2 point, at which time the patient's attention, memory and balance will be measured again as a post-test. In the final stage, the data set will be analyzed by statistical tests.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari clinic
Full name of responsible person
Arezoo Kazemi
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Sponsors / Funding sources

1

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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
Shiraz 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
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Robabeh Rostami
Position
Associate Professor
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Other areas of specialty/work
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available