

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of an Aerobic and stretching exercise program on Self-Efficacy and mental health in breast cancer women

Protocol summary

Study aim

Determining the effect of an aerobic and stretching exercise program on self-efficacy and mental health of breast cancer patients referred to Seyed al-Shohada Hospital (A) and Al-Zahra Subspecialty Clinic (S) in Isfahan.

Design

Clinical trial with control group, with parallel groups, randomized, on 64 patients. A random block is used for randomization.

Settings and conduct

The samples will be selected from those who meet the inclusion criteria from women with breast cancer referring to the chemotherapy clinic of Seyed Al-Shahada Hospital, and then they will be randomly assigned to two test or control groups. became. According to the sports program compiled by the physical education specialist, in this research, sports intervention will be carried out in the intervention group during eight weeks, three sessions per week and each session will last 35 to 40 minutes. Before the start of the intervention and after the end of the eighth week, questionnaires will be completed in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients who are aware of the diagnosis of their disease. 2. Patients who have the ability to speak and communicate verbally. 3. Cancer patients who have been diagnosed for at least one month
Exclusion criteria: 1. Patients who are treated with anticoagulant drugs 2. Patients who have been treated with radiotherapy before chemotherapy.

Intervention groups

for the intervention group; According to the sports program compiled by the physical education specialist, in this research, sports intervention will be done in the intervention group during eight weeks and three sessions per week (24 sessions in total) and each session will be 35 to 40 minutes. No sports intervention will be done for the control group and they will only receive routine care.

Main outcome variables

Self Efficacy; mental health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141127020108N4**

Registration date: **2022-07-17, 1401/04/26**

Registration timing: **prospective**

Last update: **2022-07-17, 1401/04/26**

Update count: **0**

Registration date

2022-07-17, 1401/04/26

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3778 2856

Email address

musarezaie@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.
Scientific title	Blinding (investigator's opinion)
The effect of an Aerobic and stretching exercise program on Self-Efficacy and mental health in breast cancer women	Not blinded
Public title	Blinding description
The effect of an Aerobic and stretching exercise program on Self-Efficacy and mental health	Placebo
Purpose	Not used
Supportive	Assignment
Inclusion/Exclusion criteria	Parallel
Inclusion criteria:	Other design features
Patients who are aware of their disease diagnosis. Patients who have the ability to speak and communicate verbally. Patients who are interested in participating in the study. Cancer patients who have been diagnosed for at least one month Patients who have completed at least two chemotherapy sessions.	Secondary Ids
Exclusion criteria:	empty
Patients with mental retardation, blindness, deafness, physical problems and mobility disabilities Patients with any metastases. Patients who are treated with anticoagulant drugs. Patients who have been treated with radiotherapy before chemotherapy. Patients who have a history of any type of cancer other than breast cancer.	Ethics committees
Age	1
From 18 years old to 65 years old	Ethics committee
Gender	Name of ethics committee
Female	Research Ethics Committees of Nursing, Rehabilitation and Management schools- Isfahan University of
Phase	Street address
N/A	Hazar Jarib Street, Isfahan University of Medical Sciences
Groups that have been masked	City
No information	Isfahan
Sample size	Province
Target sample size: 64	Isfahan
Randomization (investigator's opinion)	Postal code
Randomized	81746-73461
Randomization description	Approval date
In this study, we will use the block randomization method. Blocking is usually used to balance the number of samples assigned to each of the study groups. The size of all blocks is equal and we will have 4 groups of 4 blocks (including 2 participants in the intervention group and 2 participants in the control group) in this two-group experiment. In this way, we will have 16 blocks of 4 that will divide people into two groups of 32 people. Randomization tool also uses software random allocation software (Random allocation software) that these random sequence generation software in addition to simple randomization are able to generate random sequence by blocking method. Using opaque sealed envelopes, each of the random sequences created is recorded on a card, and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible	2022-07-03, 1401/04/12
	Ethics committee reference number
	IR.MUI.NUREMA.REC.1401.047
	Health conditions studied
	1
	Description of health condition studied
	Breast Cancer
	ICD-10 code
	C50
	ICD-10 code description
	Malignant neoplasm of breast
	Primary outcomes
	1
	Description
	The score obtained from the general self-efficacy questionnaire
	Timepoint
	Immediately before and immediately after the intervention
	Method of measurement
	Sherer General Self-Efficacy Scale

Secondary outcomes

1

Description

The score obtained from Depression, anxiety and stress questionnaire DASS-42

Timepoint

Immediately before and immediately after the intervention

Method of measurement

Depression, anxiety and stress questionnaire DASS-42

Intervention groups

1

Description

Intervention group: According to the sports program developed by a physical education specialist, in this research, sports intervention will be carried out in the intervention group for eight weeks, three sessions per week, each session lasting 35 to 40 minutes. In this study, the exercise protocol will be structured and at home, including three parts: warming up, aerobic exercises and cooling down. On the first day, the prepared package including the required sports equipment, a CD containing training videos of sports movements, an illustrated training booklet and an internet package with a volume of five GB will be provided to the participants. On the day of delivery of equipment and supplies, all sports movements are taught to the patients by the researcher. After the training, in order to ensure the correctness of the learning, the patients are asked to perform each exercise in the presence of the researcher. After providing the necessary training and performing physical exercises, the patients will be added to a WhatsApp group by the researcher. Before the start of the intervention, the questionnaires will be completed in person. After the end of the eighth week in the intervention group, the questionnaires will be completed online through the WhatsApp group.

Category

Other

2

Description

Control group: The control group received only routine care and completed questionnaires immediately before and after the end of the study.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyyed al-Shohada Hospital

Full name of responsible person

Amir Musa Rezaei

Street address

Motahari St., Seyyed al-Shohada Hospital

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

musarezaie@nm.mui.ac.ir

2

Recruitment center

Name of recruitment center

Al-Zahra Specialist Clinic

Full name of responsible person

Amir Musa Rezaei

Street address

Sheikh Mofid Street, Al Zahra Special Clinic

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Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mansour Siavash

Street address

Hazar Jarib Street, Isfahan University of Medical Sciences

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Postal code

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Amir Musa Rezaei

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Amir Musa Rezaei

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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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

No - There is not 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