Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Scientific title

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

Public title

The effect of an Aerobic and stretching exercise program on Self-Efficacy and mental health

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

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.

Exclusion criteria:

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.

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: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

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 participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.

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

Research Ethics Committees of Nursing, Rehabilitation and Management schools- Isfahan University of

Street address

Hazar Jarib Street, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

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., Seyed al-Shohada Hospital
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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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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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musarezaie@nm.mui.ac.ir
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 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
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