

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Investigating the effect of a combined exercise program on sleep quality and severity of fatigue in breast cancer patients undergoing chemotherapy

Protocol summary

Study aim

Determining the effect of a combined exercise program on sleep quality and fatigue severity in breast cancer patients undergoing chemotherapy

Design

A clinical trial with a control group, with parallel, randomized groups, on 64 patients, used a random number table for randomization.

Settings and conduct

Sports intervention will be performed on breast cancer patients undergoing chemotherapy referred to Seyed Al-Shohada Hospital in Isfahan. Blinding is not done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients should be aware of their diagnosis; The patient has the ability to speak and communicate verbally; Cancer patients who have been diagnosed for at least one month; Have had at least two sessions of chemotherapy. Exclusion criteria: Active mental illness and the use of drugs related to active mental illness; Having any registered metastases; Treatment with anticoagulants; Radiotherapy before chemotherapy.

Intervention groups

In the intervention group: Sports intervention will be done during eight weeks in three sessions per week and each session will last 35 to 40 minutes. In this study, exercise protocol in a structured way and at home will include three parts: warm-up, aerobic exercise and cooling. On the first day, the prepared package will include 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 gigabytes. On the day of delivery of equipment, all sports movements are taught to patients by the researcher. In the control group, routine care is performed and the questionnaires will be completed by sending the questionnaire link via SMS (online) and in

case of no internet access, by telephone.

Main outcome variables

sleep quality; Intensity of fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141127020108N1**

Registration date: **2021-12-22, 1400/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-22, 1400/10/01**

Update count: **0**

Registration date

2021-12-22, 1400/10/01

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

2021-12-22, 1400/10/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty	selects the required number of samples of even and odd numbers. All numbers will be placed in separate envelopes and all will be placed in a box. When the samples enter the study with the conditions and criteria of easy entry, then the number one card is opened for him and depending on whether this card has an even or odd number, they will be placed in one of the two groups of test or control. Thus, sampling will continue until the specified sample volume is reached. The researcher will consider the loss of samples according to the set exclusion criteria.
Trial completion date empty	Blinding (investigator's opinion) Not blinded
Scientific title Investigating the effect of a combined exercise program on sleep quality and severity of fatigue in breast cancer patients undergoing chemotherapy	Blinding description Placebo Not used
Public title Investigating the effect of a combined exercise program on sleep quality and severity of fatigue in breast cancer patients undergoing chemotherapy	Assignment Parallel
Purpose Supportive	Other design features
Inclusion/Exclusion criteria Inclusion criteria: Patients should be aware of their diagnosis. The patient has the ability to speak and communicate verbally. (Familiar with Persian) Patients do not have mental retardation, blindness, deafness, physical problems and mobility disabilities. Be interested in participating in the study. Patients in the adult age group (18 to 65 years) Cancer patients who have been diagnosed for at least one month Have had at least two sessions of chemotherapy Be treated with one of the AC regimens (adriamycin and cyclophosphamide), the CAF regimen (cyclophosphamide, adriamycin and 5-fluorouracil) or the CEF regimen (cyclophosphamide, epirubicin, 5-fluorouracil). Positioning at a functional level of zero to one based on the performance level criteria of the Eastern Participatory Oncology Group affiliated to the ECOG (WHO) Exclusion criteria: According to the diagnosis of a psychiatrist in the case, she has an active mental illness and to take drugs related to the active "mental" illness. Have any registered metastases. Treatment with anticoagulants History of any cancer other than breast cancer	Secondary Ids empty
Age From 18 years old to 65 years old	Ethics committees 1 Ethics committee Name of ethics committee Research Ethics Committees of Vice-Chancellor in Research Affairs -Medical University of Isfahan Street address Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Central Headquarters City Isfahan Province Isfahan Postal code 81746-73461
Gender Female	Approval date 2020-11-18, 1399/08/28
Phase N/A	Ethics committee reference number IR.MUI.RESEARCH.REC.1399.592
Groups that have been masked <i>No information</i>	Health conditions studied 1 Description of health condition studied Breast Cancer ICD-10 code C50 ICD-10 code description Malignant neoplasm of breast
Sample size Target sample size: 64	Primary outcomes 1 Description
Randomization (investigator's opinion) Randomized	
Randomization description Random allocation of samples in the test or control group is done using envelopes that have already been prepared using a random number table. In this way, the researcher first randomly determines that the patients to whom the odd number belongs to the experimental group and those to whom the even number belongs to the control group. He then closes his eyes and places his finger on one of the digits in the random number table. While the direction of movement is predetermined. By moving in the table of random numbers, the researcher	

Score from the sleep quality questionnaire

Timepoint
Immediately before the intervention and after the end of the eighth week

Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

1

Description
Score from the fatigue severity questionnaire

Timepoint
Immediately before the intervention and after the end of the eighth week

Method of measurement
Piper Fatigue Scale (PFS)

Intervention groups

1

Description
Intervention group: According to the exercise program compiled by a physical education specialist, in this study, sports intervention in the intervention group will be performed during eight weeks in the form of three sessions per week, each session lasting 35 to 40 minutes. In this study, exercise protocol in a structured way and at home will include three parts: warm-up, aerobic exercise and cooling. On the first day, the prepared package will include 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 gigabytes. On the day of delivery of equipment, all sports movements are taught to patients by the researcher. After the training, in order to ensure the accuracy of learning, patients are asked to perform individual exercises in the presence of the researcher

Category
N/A

2

Description
Control group: They receive only routine care and complete the questionnaires immediately before the start of the study and eight weeks later.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyed Al-Shohada Hospital in Isfahan
Full name of responsible person
Amir Musarezaie

Street address
Isfahan, Khayyam St., Nahr Farshadi Alley, Seyed Al-Shohada Hospital

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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
Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Central Headquarters
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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 Musarezaie

Position

Faculty instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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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