Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Trial completion date

empty

Scientific title

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

Public title

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

Purpose

Supportive

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

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

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 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.

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 Vice-Chancellor in Research Affairs -Medical University of Isfahan

Street address

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

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Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2020-11-18, 1399/08/28

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.592

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

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

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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
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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