

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Investigation the effectiveness of sport program on depression and fatigue in women with breast cancer under chemotherapy

Protocol summary

Study aim

The effect of exercise program on depression and fatigue in women with breast cancer undergoing chemotherapy

Design

In this study, 60 patients with breast cancer who are eligible to enter the study will be selected conveniently. Participants will be divided into two groups and each participant will be given a code.

Settings and conduct

This study will be carried out double blinded in the blood section of Imam Reza and Taleghani hospital in Kermanshah city. In this study, the Principal researcher and patients will be kept blinded to place in the intervention and control group. Patients participating in the study are aware, however, than that in the control group or the intervention group were kept blind. Sports exercises will be provided in conjunction with sports physiologists and sports physiotherapists tailored to patients' physical condition, along with slow rhythmic music in the form of film and educational brochures.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gain depression scores less than 20, based on the Beck depression inventory Exclusion criteria: No history of cancer; Under chemotherapy based on treatment protocols

Intervention groups

The intervention group, observing the film and brochure at home, 72 hours after each chemotherapy session, the exercise will be performed 3 days a week for 30 minutes for 6 weeks. The control group will not receive any sport intervention

Main outcome variables

Fatigue, Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N86**

Registration date: **2018-02-17, 1396/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-17, 1396/11/28**

Update count: **0**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-10, 1396/10/20

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effectiveness of sport program on depression and fatigue in women with breast cancer under chemotherapy

Public title

Investigation the effectiveness of sport program on depression and fatigue in women with breast cancer under chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of breast cancer at stage 0, 1, 2, 3 Have read and write literacy Gain depression scores less than 20, based on the Beck depression inventory

Exclusion criteria:

history of cancer Absence of mental disorders and dementia

Age

From **18 years** old to **54 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

60 consecutive number will be written individually on the sheet and will be placed in a container. The coupled numbers will be assigned to group A (control) and the individual numbers will be assigned into group B (intervention).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the Principal researcher and patients will be kept blinded to place in the intervention and control group. Patients participating in the study are aware, however, than that in the control group or the intervention group were kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Blvd.

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2017-12-13, 1396/09/22

Ethics committee reference number

kums.rec.1396.508

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

Fatigue

Timepoint

Before intervention, after intervention and 1 month after intervention

Method of measurement

Based on Fatigue Severity Questionnaire (FSS)

2

Description

Depression

Timepoint

Before intervention, after intervention and 1 month after intervention

Method of measurement

Beck Depression Inventory (BDI-II)

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group, observing the film and brochure at home, 72 hours after each chemotherapy session, the exercise will be performed 3 days a week for 30 minutes for 6 weeks.

Category

Behavior

2

Description

The control group will not receive any sport intervention

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Fatemeh Mostafaei

Street address

Emam Reza Hospital, Parastar Boulevard

City

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Province

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Phone

+98 83 3427 6306

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fatemeh.mostafaei1369@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Blvd.

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fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Fatemeh Mostafaei

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Dolatabad Blvd, Isar Square

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Email

fatemeh.mostafaei1369@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Parvin Abasi

Position

Faculty Member of Medical University

Latest degree

Master

Other areas of specialty/work

Nursery

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+0988338279899

Email

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Fatemeh Mostafaei

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Result and main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

What processes are involved for a request to access data/document

In a 15-day period, the documents will be sent e-mail

Comments