

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparing self-efficacy, outcome expectations for promoting the physical activity of the women with breast cancer in two groups with and without educational program

Protocol summary

Summary

The present study is a before-after experimental study with a randomized control group. The aim of the study is to examine the educational intervention effect based on self-efficacy and outcome expectations on the physical activities of the women suffering from breast cancer. The population in question are the women with breast cancer and the visitors to Seyyed Alshohada Hospital and Palliative care center (with the name of "Entekhab") in Isfahan. Inclusion criteria: (1) the final diagnosis of breast cancer by a physician, exclusion criteria: 1: therapist's prescription for a ban on attending the sessions. 2. A lack of desire to continue to participate in the study. In order to determine the sample size, the Stevens tables were used. The sample size in each group (intervention and control) is 35 patients including the loss of 10%, i.e. 70 individuals as a whole. Data collection method: 1: the self-efficacy assessment questionnaire for physical activity and outcome expectations. 2. International physical activity questionnaire (IPAQ). The former questionnaire was completed before and one month after the educational intervention, and the latter filled out before and three months after it. The experimental group underwent the educational program within at least four ninety-minute sessions with regard to the requirement identified from the patients over four weeks, while the control group was treated by normal medical care.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042117379N1**
Registration date: **2014-09-25, 1393/07/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-25, 1393/07/03

Registrant information

Name

Rahele Solymani

Name of organization / entity

Isfahan University of Medical Sciences

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+98 913 137 6746

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing self-efficacy, outcome expectations for promoting the physical activity of the women with breast cancer in two groups with and without educational program

Public title

The Physical activity of the women with breast cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1. the final diagnosis of breast cancer by a physician. 2. With individual consent and their spouse consent if they are married 3. physician's written consent to the participation of the educational program. 4. The ability to read and write the exclusion criteria: 1. the therapist's prescription for a ban on attending the sessions, 2. a lack of desire to participate in the study, 3. the absence for more than one session during the educational sessions, 4. People who are diagnosed with cognitive disorder during the educational intervention

Age

From **30 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The target group in question are the individuals visiting Seyyed Alshohada Hospital and the center for palliative medicine in Isfahan. The population of the target group will be then divided into the control and experimental group (in order to determine the test of the participants on odd days, and in order to determine the control group, the even days are considered

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib St, Health School, Isfahan

City

Isfahan

Postal code

8174673461

Approval date

2014-01-08, 1392/10/18

Ethics committee reference number

3082/ 12/3

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

c50

ICD-10 code description

50 Malignant neoplasm of breast

Primary outcomes

1

Description

self-efficacy for physical activity

Timepoint

Before the intervention and one month after it

Method of measurement

The standard self-efficacy questionnaire for physical activity by Bandura

2

Description

outcome expectation for physical activity

Timepoint

Before the intervention and one month after it

Method of measurement

the questionnaire tested

Secondary outcomes

1

Description

Physical activity

Timepoint

Before the intervention and three month after it

Method of measurement

the standard physical activity measurement questionnaire

Intervention groups

1

Description

The first session is devoted to identifying patients' need for education in the experimental group, then they receive education during at least 4 educational ninety minute sessions with respect to the barriers of self-efficacy in physical activity, energy management, stress management, lymphedema prevention, and other topics mentioned in the group. The training sessions are presented by PowerPoint and the relevant experts for each topic. The educational activities are intended for

the promotion of self-efficacy, brainstorming strategies, verbal persuasion, successor experience, framing question in the group.

Category

Rehabilitation

2

Description

There is no special arrangement for the control group, except for normal medical care

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Entekhab Supportive and Palliative care center

Full name of responsible person

Rahele Solymani

Street address

NO.29, Aminodoleh Alley, Sahid Baghi Alley, Shahid Motahari St, Isfahan, Iran

City

Isfahan

2

Recruitment center

Name of recruitment center

Seyyed Alshohada Hospital

Full name of responsible person

Rahele Solymani

Street address

Motahari Ave, Saeb St, toward Marnans Bridge, Shiris Bridge, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Peyman Adibi

Street address

Hezar Jarib St, Vice chancellor for research, Isfahan University of Medical Sciences

City

Isfahan

Grant name

هنوز اعلام نشده است

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

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Position

Master student of Health Education and Social Health Promotion

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty