

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Clinical Trial on Effectiveness of Otago Exercise Training Programme on Multidimensional Fatigue Syndrome among Elderly Patients with Cancer

Protocol summary

Summary

This study will be conducted to evaluate the efficacy of Otago Exercise home training programme on Multidimensional Fatigue Syndrome (MFS) among female elderly patients with breast cancer in the Khansari hospital in Arak. The study sample will be 82 subjects whom will be divided in two control and experimental groups. The main inclusion criteria are being female, 60 years old and above and live with a female caregiver aged 15-50 with health literacy. Moreover, the main exclusion criteria are acute cardiac, pulmonary and orthopedic disease that have banned subjects from exercise. After completing the primary assessments, the Multidimensional Fatigue Syndrome in both groups, Otago home exercise training will be implemented on the intervention group and routine health education will be given to control group. Subjects of the study will be assigned randomly by random number table. Subjects of the study will be blinded to being in control or intervention group. After 12 weeks both groups will be assessed for MFS checked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016121216285N3**

Registration date: **2017-04-11, 1396/01/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-11, 1396/01/22

Registrant information

Name

Ali Dadgari

Name of organization / entity

Shahrood University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research; Sharoud University of Medical Sciences

Expected recruitment start date

2017-03-05, 1395/12/15

Expected recruitment end date

2017-05-15, 1396/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial on Effectiveness of Otago Exercise Training Programme on Multidimensional Fatigue Syndrome among Elderly Patients with Cancer

Public title

Clinical trial on Effectiveness of Otago Exercise Training Programme on Multidimensional Fatigue Syndrome among Elderly Patients with Cancer

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Age 60 years old and above Being female MMSE more than 12 Having a care giver in ages range between 15 and 50 years old with health literacy
Exclusion Criteria: The presence of acute cardiac,

pulmonary, orthopedic or any disease which ban the subjects for doing exercises such as anemia

Age

From **60 years** old to **100 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of sharoud University of Medical Sciences

Street address

Head Quarter of Sharoud university of medical sciences, Hafte Tir Square, Shahroud

City

Shahroud

Postal code

3614773955

Approval date

2017-01-21, 1395/11/02

Ethics committee reference number

IR.SHMU.REC.1395.157

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

CD50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Multidimensional Fatigue Syndrom

Timepoint

Before intervention- After intervention

Method of measurement

Multidimensional Fatigue Inventory Syndrom

Secondary outcomes

1

Description

Quality of Sleep

Timepoint

Before and After Intervention

Method of measurement

assessed by Sleep Quality Questionnaire

2

Description

Neuromuscular pain

Timepoint

Before and after the intervention.

Method of measurement

Using Pain Questionnaire

3

Description

Feeding problems and weight loss

Timepoint

Before and after the intervention.

Method of measurement

Using BMI

4

Description

Stress

Timepoint

Before and after the intervention.

Method of measurement

Using Stress Questionnaire

Intervention groups

1

Description

Intervention group: Otago exercise is a training programme designed and conducted in University of Otago, New Zealand. The exercise will be implemented for 12 weeks, 5 days per week for 40-60 minutes. In control group. General health education will be provided to subjects based on instructions of Ministry of Health, Treatment and Medical Education for elderly people.

Category

2

Description

In subjects in intervention group Otago Exercise Programme will be implemented. In control group general health education will be given

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah khansari Hospital

Full name of responsible person

Nafise Salehi-old graduate student-student

Street address

Markazi Province, Arak, the Street University

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research; Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hassan Emamian

Street address

Head Quarter of Shahroud University of Medical Sciences, Hafte Tir Square, Shahroud

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Shahroud

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research; Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Ali Dadgari

Position

PhD in Gerontology

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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty