# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of exercise and nutrition educational program on severity of fatigue in adolescents' cancer patients undergoing chemotherapy

## Protocol summary


**Summary**

1)Objective: To determine the effect of training exercise and nutrition on the severity of fatigue caused by cancer in adolescents who are undergoing chemotherapy in the oncology department of Amir hospital in shiraz , Iran between2015/16. 2)Design: This randomized clinical trial is not blind. 3) Methodology: 110 adolescents' patients between the age of 10 to 18 years are eligible for inclusion in this study and are randomly divided into groups of control and test. The control group filled out a questionnaire before the study about fatigue, but does not receive any training. In the test group they filled out a questionnaire before the study on the subject of fatigue but they received 6 weeks of training and diet. They are told to exercise at home for 20 minutes daily. A week after the end of training both groups filled out the questionnaire of fatigue once again. 4) Study samples : the study samples includes cancer patients who are undergoing chemotherapy. The main condition for entry and withdrawal of participants are; The main criteria for inclusion: Age between 10 to 18 years of age, at least a month has pased from the onset of diagnosis, have not history of heart disease, diabetes, underlying or congenital disease; The main exclusion criteria: lack of desire to continue cooperation, patients who have an amputee, patients who are neurologically impaired due to disease or treatment complications. 5) Intervention: in both groups before the study they completed a questionnaire and the test group is given exercise and nutrition training for six weeks, both groups filled out the questionnaire and fatigue severity is checked. 6) The main outcomes: Fatigue severity caused by cancer.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201406168124N3**

Registration date: **2016-04-08, 1395/01/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

**Registration date**

2016-04-08, 1395/01/20

**Registrant information**


**Name**

Zahra Molazem

**Name of organization / entity**

Shiraz University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 71 1647 4254

**Email address**

molazem@sums.ac.ir


**Recruitment status**

**Recruitment complete**


**Funding source**

Shiraz University of Medical Sciences


**Expected recruitment start date**

2016-02-13, 1394/11/24

**Expected recruitment end date**

2016-05-14, 1395/02/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of exercise and nutrition educational program on severity of fatigue in adolescents' cancer patients undergoing chemotherapy

**Public title**

The effect of exercise and nutrition educational program on severity of fatigue in adolescents' cancer patients undergoing chemotherapy

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: patients who are undergoing chemotherapy؛ in age range of 10 to 18 years old؛ Duration of illness is at least a month from the onset of diagnosis؛ Willingness to participate؛ physical ability؛ Havinge not participated in similar study؛ having no history of heart failure, diabetes, Underlying and congenital disease. Exclusion criteria: Lack of willingness to cooperate in the research؛ not being present in a meeting of the pre-test and or post-test؛ Lack of participatione in a theoretical or practical training sessions؛ patients who have a physical amputation؛ patients who are ill or the effects of treatment creates a neurological disorders.

**Age**

From **10 years** old to **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **110**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**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**

Ethics Committee of Shiraz University of Medical Sciences

**Street address**

Zand Street, Shiraz

**City**

Shiraz

**Postal code**

7134814336

**Approval date**

2016-01-24, 1394/11/04

**Ethics committee reference number**

IR.SUMS.REC.1394.179

## Health conditions studied

### 1

**Description of health condition studied**

Cancer

**ICD-10 code**

C80.0

**ICD-10 code description**

Malignant neoplasm without specification of site

## Primary outcomes

### 1

**Description**

fatigue

**Timepoint**

Before and after the intervention

**Method of measurement**

Fatigue severity scale questionnaire MFI

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

In the experimental group they are given exercise and diet training.

**Category**

Other

### 2

**Description**

In the control group no training is given.

**Category**

N/A

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Oncology Hospital Amir

**Full name of responsible person**

Zahra Keshtkar

**Street address**

Station 11, Culture City, Shiraz

**City**

Shiraz

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Vice Chancellor for Research, Shiraz University of Medical Sciences

**Full name of responsible person**
Doctor Sayed Basir Hashemi

**Street address**
Zand Street, Shiraz

**City**
Shiraz

**Grant name**
94/484203

**Grant code / Reference number**
94-7643

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

**Title of funding source**
Vice Chancellor for Research, Shiraz 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**
School of Nursing Hazrat Fatima(sa), Shiraz University of Medical Sciences

**Full name of responsible person**
Zahra Keshtkar

**Position**
Special Nursing Student

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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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*