Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 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

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Iran (Islamic Republic of)

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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
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Full name of responsible person
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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