

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of lifestyle education on increasing the level of awareness and performance of cancer patients in reducing complications during chemotherapy

Protocol summary

Study aim

Determining the effect of lifestyle education on increasing the level of awareness and performance of cancer patients in reducing complications during chemotherapy

Design

A clinical trial with a control group, with parallel groups, outcome-assessor blinded, randomized, phase 3 on 66 patients. Random Allocation software is used for randomization.

Settings and conduct

Cancer patients referred to Tajrish Martyrs Hospital in Tehran who are undergoing chemotherapy are included in the study. The outcome assessor does not know the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Having cancer based on the pathology report 2 . Candidate for chemotherapy (have not yet started chemotherapy or have completed at least one course of chemotherapy) 3. Willingness to participate in the training class on healthy lifestyle recommendations during chemotherapy. Exclusion criteria: 1. Receive other treatments such as radiotherapy at the same time as chemotherapy. 2. Do not want to be trained 3. Recent participation in similar educational and research meetings

Intervention groups

The patients in the intervention group, in addition to standard treatments and recommendations, during an educational session, healthy lifestyle recommendations during the chemotherapy period along with simple and practical solutions for cancer patients who are candidates for chemotherapy (still chemotherapy) have not started or have received at most one course of chemotherapy) is explained. The taught materials are also provided to the participants in typed form. The patients in the control group receive the usual

treatments and recommendations and do not participate in the training session.

Main outcome variables

Awareness and performance of patients in reducing the side effects of chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150825023753N20**

Registration date: **2023-11-14, 1402/08/23**

Registration timing: **prospective**

Last update: **2023-11-14, 1402/08/23**

Update count: **0**

Registration date

2023-11-14, 1402/08/23

Registrant information

Name

Mohammad Mahdi Parvizi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3212 5592

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-16, 1402/08/25

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of lifestyle education on increasing the level of awareness and performance of cancer patients in reducing complications during chemotherapy

Public title

Investigating the effect of lifestyle education on increasing the level of awareness and performance of cancer patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Having cancer based on the pathology report Candidate for chemotherapy (have not yet started chemotherapy or have completed at least one course of chemotherapy) Willingness to participate in the training class on healthy lifestyle recommendations during the course of chemotherapy

Exclusion criteria:

Receive other treatments such as radiotherapy at the same time as chemotherapy. Refuse to receive training Recent participation in similar educational and research meetings

AgeFrom **18 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **66****Randomization (investigator's opinion)**

Randomized

Randomization description

By using random allocation software, consecutive permutation blocks with the size of 6 people in each block are made and the patients are divided into two groups A (first treatment method) and B (second treatment method).

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the clear difference in the treatment method in each study group, blinding is done only at the level of the outcome assessor. The interventionist is different from the outcome assessor. There is no possibility of blinding the patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee on Biomedical Research of Shahid Beheshti University of Medical sciences

Street address

Shahid Beheshti University of Medical sciences, Daneshju Blv.

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2023-06-18, 1402/03/28

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.038

Health conditions studied**1****Description of health condition studied**

Cancer

ICD-10 code

C00-C97

ICD-10 code description

Malignant neoplasms

Primary outcomes**1****Description**

Level of awareness about side effects during chemotherapy

Timepoint

Before and after training

Method of measurement

Life style awareness questionnaire during chemotherapy

2**Description**

Performance level about side effects during chemotherapy

Timepoint

Before training and after three courses of chemotherapy

Method of measurement

Questionnaire of lifestyle performance level during chemotherapy

Secondary outcomes

1

Description

Patient's quality of life

Timepoint

Before training and after three courses of chemotherapy

Method of measurement

EORTC Quality of Life Questionnaire QLQ-C30

Intervention groups

1

Description

Intervention group: In addition to common treatments and recommendations, during an educational session, healthy lifestyle recommendations during chemotherapy along with simple and practical solutions for cancer patients who are candidates for chemotherapy (have not yet started chemotherapy) or have received at most one course of chemotherapy) is explained. The taught materials are also provided to the participants in typed form. The educational content includes explanations about the treatment process (briefly about chemotherapy and its side effects), answers to participants' questions, correcting misconceptions about chemotherapy, and complete explanations about the appropriate lifestyle during chemotherapy. Lifestyle training includes recommendations on food and drinks, the amount of movement and rest, the amount of sleep and wakefulness, the control of constipation, diarrhea, nausea, and vomiting, and the temperament of patients in this course, as well as common medicine recommendations based on the content of the "Nutrition and Cancer" training course provided by WageningenX as well as the results of recent studies. It is presented to the participants through lectures, group discussions, questions and answers, and the exchange of information and experiences.

Category

Lifestyle

2

Description

Control group: They receive common treatments and recommendations and do not participate in the training session.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohay-e-Tahrish Hospital

Full name of responsible person

Dr. Ghazaleh Heydarirad

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Tajrish Square, Shohaday-e-Tejarish Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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Shams Alley, Vali-e-Asr Street, Shahid Beheshti University of Medical Sciences

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Mahdi Parvizi

Position

Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data and the result of the clinical trial

When the data will become available and for how long

One year later

To whom data/document is available

Researchers

Under which criteria data/document could be used

After the publication of the article based on the clinical trial, it will be possible to share the data. The recipients of the data can use the data by obtaining permission from the project managers. The managers of this project will allow the data to be used in secondary data analysis studies and systematic reviews.

From where data/document is obtainable

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

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

Data requesters can submit their request by sending an email to each of the administrators that their names and emails have been entered into this system.

Comments