

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of a Multimodal Interventions on the Quality of Life, Physical Performance and Body Composition of Adult Patients with Cachexia Caused by Gastric and Esophageal Cancer: a Clinical Trial

Protocol summary

Study aim

Investigating the effect of a multiple intervention on quality of life, physical performance and body composition of patients

Design

The clinical trial has two intervention and control (supportive) groups, randomization will be done in a simple way and through lottery on 40 patients.

Settings and conduct

Elastic resistance training will be held online. Food recommendations, Mediterranean food menu, considerations during exercise, and tips on adherence to exercise will be provided to patients in the form of brochures. After the written consent forms are filled by the patients, the strength and physical performance test will be done at the Top Technique Club. A CT scan will be performed to measure the body composition of patients in Luqman Hakim Hospital. Questionnaires; Clinical, Karnofsky, Sharkey physical activity, quality of life, fatigue intensity, nutritional status, food frequency will be filled over the phone. 150 minutes of aerobic exercise with low to moderate intensity per week will also be prescribed according to the conditions and interests of the patients.

Participants/Inclusion and exclusion criteria

Entry requirements: Patients with cachexia caused by stomach and esophagus cancer, the treatment of the patients has been completed and they have permission from the doctor. Exclusion criteria: change from oral nutrition to parenteral or parenteral nutrition and major surgery in the last 4 weeks.

Intervention groups

Effect of elastic resistance training, Mediterranean diet and behavior change

Main outcome variables

Elastic resistance exercises; Mediterranean diet; Quality of Life; fatigue; physical performance; Muscle strength;

body fat percentage; visceral fat; muscle mass

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240406061430N1**

Registration date: **2024-05-05, 1403/02/16**

Registration timing: **prospective**

Last update: **2024-05-05, 1403/02/16**

Update count: **0**

Registration date

2024-05-05, 1403/02/16

Registrant information

Name

Fatemeh Faraji Sefidkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 3358 7143

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-21, 1403/03/01

Expected recruitment end date

2025-06-21, 1404/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of a Multimodal Interventions on the Quality of Life, Physical Performance and Body Composition of Adult Patients with Cachexia Caused by Gastric and Esophageal Cancer: a Clinical Trial

Public title

A Multiple Intervention on Adult Patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Patients with Gastric and Esophageal Cancer 2. Patients with Cachexia 3. Successful Eligibility for First-Line Radiotherapy or Chemotherapy Guidelines 4. Patients' Treatment Process must be Complete 5. Karnofsky Functional Status at least 70% 6. Nutritional Drugs 7. Patients without Uncontrolled Acute Underlying Diseases, Kidney Failure, Disease, Acquired Immunodeficiency Syndrome, Intestinal Diseases or Chronic Disease Treatments that Cause Cachexia Related to the Disease 8. Male and Female Patients 18 years and Older 9. Willing Patients To Participate in the Study 10. Having a Doctor's Permission to Participate in Diet and Exercise 11. Having Online Classes.

Exclusion criteria:

1. Patients Who Die 2. Patients Who Comply with Less than 60% of the Recommended Nutrition 3. Changing the Route of Oral Nutrition to Enteral or Intravenous Nutrition 4. Reluctance to Continue the Study 5. Changing the Treatment Protocol 6. Major Surgery in the Last 4 Weeks

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

It will Be Done by Simple Random Sampling and Through Lottery, in which a Number or Code is Prepared for Each Member of the Community, then the Numbers are Written on Pieces of Paper. The Pieces of Paper are Placed in a Container and Mixed well, then a Sample of a Certain Volume is Selected from It.

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 Shahid University

Street address

Shahed university, opposite to the Holy shrine of Imam Khomeini, Khalij Fars Expressway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2024-03-09, 1402/12/19

Ethics committee reference number

IR.SHAHED.REC.1402.146

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

Cachexia caused by gastric and esophagus cancer

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Mediterranean Diet

Timepoint

Before and After

Method of measurement

PG-SGA Nutritional Status Questionnaire

2**Description**

Quality of Life

Timepoint

Before and After

Method of measurement

EOPTC-QLQ-C30 Quality of Life Questionnaire

3**Description**

Tiredness

Timepoint

Before and After

Method of measurement

FSS Fatigue Intensity Questionnaire

4

Description

Physical Performance

Timepoint

Before and After

Method of measurement

Getting up and Sitting for 30 Seconds

5

Description

Upper Limb Muscle Strength

Timepoint

Before and After

Method of measurement

5 Repetition Maximum Chest Press Test

6

Description

Lower Limb Muscle Strength

Timepoint

Before and After

Method of measurement

5 Repetition Maximum Leg Press Test

7

Description

Body Fat Percentage

Timepoint

Before and After

Method of measurement

Abdominal CT Scan Without Contrast

8

Description

Visceral Fat

Timepoint

Before and After

Method of measurement

Abdominal CT Scan Without Contrast

9

Description

Muscle Mass

Timepoint

Before and After

Method of measurement

Abdominal CT Scan Without Contrast

Secondary outcomes

1

Description

Mediterranean Diet

Timepoint

Before and After

Method of measurement

FFQ Food Frequency Questionnaire

2

Description

Mediterranean Diet

Timepoint

The Second, Fourth, Sixth and Eighth Week of Study

Method of measurement

24-Hour Food Reminder Questionnaire

3

Description

Quality of Life

Timepoint

Before and After

Method of measurement

Sharkey Physical Activity Questionnaire

Intervention groups

1

Description

In addition to their usual treatment, they will receive resistance training with exercise bands, a Mediterranean diet, a prescription for 150 minutes of low-to-moderate aerobic exercise, and exercise adherence tips to change behavior toward an active lifestyle.

Category

Rehabilitation

2

Description

Control group: They do not receive any intervention other than their usual treatment

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical Research Development Unit of Luqman Hakim Hospital

Full name of responsible person

Omidre Rezaei Mirqaid

Street address

Lashgar intersection, Special street, Luqman Hakim hospital, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Shahriar Bijani

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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

Shahed University

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

Shahed University

Full name of responsible person

Fateme Faraji Sefidkhani

Position

Collegian

Latest degree

Bachelor

Other areas of specialty/work

Physiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to

make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable