

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 21 3358 7143

##### Email address

faraji4156@gmail.com

##### 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

#### **City**

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#### **Postal code**

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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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**Fax**

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**Email**

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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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Associate Professor

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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