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
Tehran
Province
Tehran
Postal code
1333635445
Phone
+98 21 5541 9005

Email
loghman.hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Shahriar Bijani
Street address
Shahed University, opposite the Holy shrine of Imam Khomeini, Persian Gulf Expressway,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
15875-5794
Phone
+98 21 4110 5121
Fax
+98 21 4110 5121
Email
info@shahed.ac.ir
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
Street address
No. 200, Som East Alley, Qiamadasht, Valiasr St., 4th Floor, Unit 10
City
Tehran
Province
Tehran
Postal code
1867174765
Phone
+98 21 3358 7143
Email
faraji4156@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Amin Isanezhad
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiology
Street address
Shahed University, opposite to the Holy shrine of Imam Khomeini, Khalij Fars Expressway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5121 2442
Email
A.isanezhad@shahed.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Fatemeh Faraji Sefidkhani
Position
Collegian
Latest degree
Bachelor
Other areas of specialty/work
Physiology
Street address
No. 200, Unit 10. South Valiasr St., East Third Alley, Qiyamdasht, Tehran
City
Tehran
Province
Tehran
Postal code
1867174765
Phone

+98 21 3358 7143
Fax
Email
faraji4156@gmail.com

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