Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of individual nutrition counseling and family education on quality of life, sleep, weight changes, stress, anxiety and depression in patients with gastric cancer after total gastrectomy

Protocol summary

Study aim

The effect of nutrition education on quality of life, sleep, weight changes, stress and anxiety, and depression in patients with gastric cancer after total gastrectomy

Design

The clinical trial in which the sampling is the random allocation and the minimum sample size required for each group was determined by dropping the samples with a probability of ten percent, 33 people for each group, and a total of 66 people. Data are analyzed using STATA version 15, MP version.

Settings and conduct

patient in Imam Khomeini Hospital after gastrectomy according to inclusion and exclusion criteria and personal satisfaction were included in the study and the group under consultation initially includes a face-to-face training session with the patient and preferably with close relatives after surgery and The stability of the situation is the adjustment of an individual diet plan for each patient on a weekly basis, during which the necessary follow-ups and answers to the patient's questions are performed during the week. The patient's companions will receive training every two weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of gastric cancer, age 20-65 years, total gastrectomy exclusion criteria: Patients with chronic diseases such as cardiovascular disease, mental illness or impaired consciousness, cancer metastasis to other organs (end-stage (IV) gastric cancer), diseases that may affect their nutritional status Like diabetes, long hospital stay.

Intervention groups

Nutrition counseling protocol interventions according to the American Cancer Nutrition Guideline, to treat them by a nutritionist who is responsible for research. the control group has no training program and receives only routine nursing care.

Main outcome variables

Quality of life; quality of sleep; general health; stress scale; anxiety and depression; assessment of nutritional status and weight changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150902023861N9**
Registration date: **2023-02-13, 1401/11/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-13, 1401/11/24**
Update count: **0**

Registration date

2023-02-13, 1401/11/24

Registrant information

Name

Mitra Zarrati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

zarrati.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-05, 1401/03/15

Expected recruitment end date

2023-08-22, 1402/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of individual nutrition counseling and family education on quality of life, sleep, weight changes, stress, anxiety and depression in patients with gastric cancer after total gastrectomy

Public title
The effect of individual nutrition counseling and family education on improving life and weight changes in patients with gastric cancer after total gastrectomy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of gastric cancer Age between 20 to 65 years Total gastrectomy
Exclusion criteria:
Patients with chronic diseases such as cardiovascular,Mental illness or disturbance of consciousness Cancer metastasis to other organs (end stage (IV) gastric cancer) Diseases that may affect their nutritional status, such as diabetes Long-term hospitalization.
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
For the random allocation of people, it will be done using the minimization method based on gender variables and in the form of balanced blocks. For this purpose, we have 6 pages of paper, on 3 of which the word I, which stands for Intervention, and on 3 of them, the word C, which stands for Control, is written. Then these are placed in a container and randomly extracted from this information box of these people until six pieces of paper are extracted from this package. Again, this operation is repeated until all the sample volume is taken. Then the participants in the selected blocks will be selected in a balanced way and based on gender according to the predetermined table. To balance the blocks based on sex, two pieces of paper written one of them with the word F, which stands for female, and the other with the word M, which stands for male, are then placed in the compartment and drawn randomly by replacing so that the ratio of women to men is considered to be 2 to 1 in the first block of 6 tuple and 1 to 2 in the next block of 6 tuple until the end, for this purpose the first half of the block of 6 tuple where the ratio of women to men is 2 to 1 If the first two people are randomly selected as men, in order to maintain the ratio of 2 to 1, we will consider the third person as a woman. We will determine the second half of the block based on the first half of the block. In the next block of 6 tuple, this time the ratio is reversed and the ratio of women to men is considered 1 to 2. Again, the lot is drawn by replacing and if the first person is a woman and the second person is a man, the third person is chosen as a woman to maintain the ratio, and this process continues until the end. The gender variable is considered a potentially confounding variable and the minimization method was used for the least confounding effect in the study. According to previous similar studies and research objectives, randomization will be done based on gender.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Educational and Guidance

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, next to the Milad hospital, the intersection of Sheikh Fazlallah and Shahid Chamran, Hemmat expressway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2022-05-08, 1401/02/18
Ethics committee reference number
IR.IUMS.REC.1401.087

Health conditions studied

1

Description of health condition studied
gastric cancer
ICD-10 code
C16

ICD-10 code description
Malignant neoplasm of stomach

Primary outcomes

1

Description
Quality of Life
Timepoint
before intervention and 4, 8 weeks after intervention
Method of measurement
QLQ-STO22 and QLQ-C30 quality of life questionnaires

Secondary outcomes

1

Description
sleep quality
Timepoint
before intervention and 4 , 8 weeks after intervention
Method of measurement
Peters burg Sleep Quality Questionnaire (PSQI)

2

Description
General Health
Timepoint
before intervention and 4 , 8 weeks after intervention
Method of measurement
General Health Questionnaire (GHQ)

3

Description
Stress-Depression-Anxiety
Timepoint
before intervention and 4 , 8 weeks after intervention
Method of measurement
Stress Anxiety Depression Scale (DASS)

4

Description
Nutritional status of cancer patients
Timepoint
before intervention and 4 , 8 weeks after intervention
Method of measurement
The Patient-Generated Subjective Global Assessment Questionnaire

5

Description
Weight changes
Timepoint
before intervention and 4 , 8 weeks after intervention
Method of measurement
Weight (kg), waist and hip circumference (cm)

Intervention groups

1

Description
The intervention group receives individual nutrition counseling and training from family members. Patients in Imam Khomeini Hospital are admitted to the study after total gastrectomy according to the research criteria. After surgery and stabilization, a face-to-face training session is held with the patient and preferably with the participation of close relatives. After discharge, a weekly individual diet plan for each patient and training on how to deal with and reduce postoperative complications. The protocol procedure will be performed according to the American gastrectomy guideline. During the week, the necessary follow-ups and answering of the patient's questions will be done via video calls. In addition, the patient's companions will be trained once every two weeks. At the beginning of the study, patients are evaluated through questionnaires at weeks 4 and 8.
Category
Lifestyle

2

Description
Control group: Without any nutrition intervention, During hospitalization, patients routinely receive general nutrition education related to gastrectomy from the treatment staff. This group is also evaluated at the beginning of the study and during the 4th and 8th weeks.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr.Seyed Rohollah Miri
Street address
End of Keshavarz Boulevard, Dr. Gharib Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Shahid Hemmat Highway between Sheikh Fazlollah Nouri and Shahid Chamran Iran University of Medical Sciences Razi International Conference Center Public Relations
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr.Mitra Zarrati
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
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zarrati.m@iums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available