Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of patient-centered education on the self-care ability and quality of life of the elderly with gastrointestinal cancers

Protocol summary

Study aim

Determining the effect of patient-centered education on self-care ability and quality of life of elderly people with gastrointestinal cancers

Design

The clinical trial has a control group, with parallel groups and no blinding. The sampling method is available and consecutive and based on the inclusion and exclusion criteria until the sample size is completed. Random allocation will be done using the block randomization method. Sampling will be done in the oncology department of Shahid Rahimi Hospital, Khorramabad.

Settings and conduct

The student will go to the oncology department for familiarization and sampling. After sampling and collecting data with a questionnaire, the intervention will consist of 8 sessions, including 1 interview session with the patient, followed by 6 sessions of the supportive education program, and 1 session of evaluation and feedback of the educational-supportive program. The sessions will be held one after the other in person and virtually at one-week intervals. At the end of 2 weeks after the completion of the interventions, the questionnaire will be provided again to the experimental and control groups.

Participants/Inclusion and exclusion criteria

Entry requirements: Age over 60 years, gastrointestinal cancer, having completed at least one session and having at least 6 sessions of chemotherapy remaining, access to a smartphone, and adequate hearing and vision. Exclusion criteria: Unwillingness to continue cooperation, oncology emergencies, patients in need of palliative care, known mental illness, sudden discontinuation of treatment, death, or emigration.

Intervention groups

Intervention group: After familiarization, training will be provided based on a designed model and the patient's own needs. Control group: Routine care without training.

Main outcome variables

Self-care ability. Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170514033961N11**
Registration date: **2025-04-27, 1404/02/07**
Registration timing: **prospective**

Last update: **2025-04-27, 1404/02/07**
Update count: **0**

Registration date

2025-04-27, 1404/02/07

Registrant information

Name

Mandana Saki

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3331 6465

Email address

m.saki@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-05, 1404/02/15

Expected recruitment end date

2025-06-05, 1404/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of patient-centered education on the self-care ability and quality of life of the elderly with gastrointestinal cancers

Public title
The effect of patient-centered education on the self-care ability and quality of life of the elderly with gastrointestinal cancers

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Over 60 years of age Having metastatic or non-metastatic gastrointestinal cancer (such as stomach cancer, esophageal cancer, colon cancer, and colorectal cancer) At least one session has passed and at least 6 sessions of chemotherapy remain. Smartphone access Adequate hearing and vision ability

Exclusion criteria:
Unwillingness to continue cooperation Oncology emergencies Patients in need of palliative care Having known mental illnesses (bipolar, etc.) or having dementia Abrupt discontinuation of treatment at the discretion of the physician or patient, death, or migration

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The allocation of samples to groups is done using the Block Randomization method. In order to equalize the distribution of confounding variables of cancer type (gastric cancer, esophageal cancer, colon cancer, and colorectal cancer), first, classes are created based on these variables, such as female/male class and cancer based on metastatic or non-metastatic, and then the block randomization method is used to assign patients to two groups using random blocks of 4. 6 different combinations of 4-blocks (AABB- ABAB- ABBA- BBAA- BABA- BAAB) are created and randomly selected using the Blockrand package of R software, and the random sequence will be formed as a sequence of letters A and B.

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 Lorestan University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Lorestan University of Medical Sciences University Campus Complex, Khorramabad-Borujerd Road, Khorramabad, Lorestan

City
Khorramabad

Province
Lorestan

Postal code
6813833946

Approval date
2025-03-05, 1403/12/15

Ethics committee reference number
IR.LUMS.REC.1403.475

Health conditions studied

1

Description of health condition studied
Gastrointestinal (esophagus) cancer

ICD-10 code
C15

ICD-10 code description
Malignant neoplasm of esophagus

2

Description of health condition studied
Gastrointestinal (stomach) cancer

ICD-10 code
C16

ICD-10 code description
Malignant neoplasm of stomach

3

Description of health condition studied
Gastrointestinal (colon) cancer

ICD-10 code
C18

ICD-10 code description
Malignant neoplasm of colon

4

Description of health condition studied
Gastrointestinal (rectal) cancer

ICD-10 code
C20
ICD-10 code description
Malignant neoplasm of rectum

Primary outcomes

1

Description
Quality of life
Timepoint
Before the start of the intervention and two weeks after the end of the intervention
Method of measurement
Quality of Life Questionnaire-Core 30

2

Description
Self-care ability
Timepoint
Before the start of the intervention and two weeks after the end of the intervention
Method of measurement
Questionnaire to assess the ability of self-care specifically for patients with colorectal cancer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, the educational intervention for patients will consist of 8 30- to 45-minute sessions, both in-person and virtual. The sessions will be held at weekly intervals, one-on-one, both in-person and virtual. Each educational session will include a lecture and a question and answer session. Educational brochures will also be provided to them.
Category
Lifestyle

2

Description
Control group: In this group, an intensive training session is held after the final stage of data collection.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Lorestan University of Medical Sciences
Full name of responsible person
Mandana Saki
Street address
5 kilometers of Khorram Abad Borujard road
City
Khorramabad
Province
Lorestan
Postal code
68149-93165
Phone
+98 66 3312 0174
Fax
+98 66 3312 0173
Email
mandana_saki@yahoo.com
Web page address
http://research.lums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Bahram Kamrei
Street address
Lorestan University of Medical Sciences, in front of Kahrizak village, 5 km of Khorramabad-Boroujerd road, Khorramabad, Lorestan, Iran
City
khorramabad
Province
Lorestan
Postal code
381251698
Phone
+98 66 3312 0172
Fax
+98 66 3312 0173
Email
research@lums.ac.ir
Web page address
http://research.lums.ac.ir/index.php?module=web_directory&wd_id=4664
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khoram-Abad University of Medical Sciences
Proportion provided by this source
1
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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Mandana Saki

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
5 km of Khorram Abad-Boroujerd road

City
Khorramabad

Province
Lorestan

Postal code
6819834525

Phone
+98 66 3331 6465

Fax
+98 66 3312 0140

Email
mandana_saki@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Mandana Saki

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
5 km of Khorram Abad-Boroujerd road

City
Khorramabad

Province
Lorestan

Postal code
6819834525

Phone
+98 66 3331 6465

Fax
+98 66 3312 0140

Email
mandana_saki@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Mandana Saki

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
5 km of Khorram Abad-Boroujerd road

City
Khorramabad

Province
Lorestan

Postal code
6819834525

Phone
+98 66 3331 6465

Fax
+98 66 3312 0140

Email
mandana_saki@yahoo.com

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
All potential data is released after unidentifiable individuals in the form of original message information.

When the data will become available and for how long
The access period will start 6 months after printing.

To whom data/document is available
All researchers, lecturers, medical students can receive the published article from the relevant journal.

Under which criteria data/document could be used
Unidentifiable data will be made available to health researchers for the study of meta-analysis

From where data/document is obtainable
Send Saki Mandana an email m.saki@modares.ac.ir

What processes are involved for a request to access data/document
After sending the documents by the applicant's researcher via email, the data will be send two weeks

later.

Comments