Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of tele-palliative care on hope and fear of disease progression in Gastrointestinal cancer patients: A parallel randomized clinical trial

Protocol summary

Study aim
Determining the effect of a tele-palliative care on Hope and Fear of disease progression in Patients with Gastrointestinal cancer

Design
A parallel randomized clinical trial was conducted with 74 patients (37 in the intervention group and 37 in the control group), without blinding. Randomization was performed using sealed envelopes.

Settings and conduct
The tele-palliative care educational program was delivered in the form of video clips, once a week for six weeks, via the WhatsApp platform to participants in the intervention group in the cities of Shahroud and Semnan. The Hope and Fear of Disease Progression questionnaires were completed for both groups immediately after and one month following the completion of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Ages 20-60 years old, Confirmed diagnosis of stage II or III gastrointestinal cancer, Literate, possessing a mobile phone equipped with WhatsApp software on a smartphone, Having undergone at least one chemotherapy session. Exclusion criteria: Having severe mental disorders (diagnosed and confirmed by a physician), Taking neuroleptic drugs, Having a critical physical condition due to cancer, Having uncorrectable visual and hearing impairments, Participating in any palliative care program during the course of the illness.

Intervention groups
In the intervention group, participants will receive the palliative care intervention through the WhatsApp application, consisting of one session per week for six weeks, with each session lasting 30 to 45 minutes in the form of educational video clips. Participants in the control group will continue to receive the same treatments they were receiving prior to the study. After the completion of the intervention and data collection, the educational program will also be shared with the control group.

Main outcome variables
Hope, Fear of disease progression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251118068042N1**
Registration date: **2025-12-16, 1404/09/25**
Registration timing: **prospective**

Last update: **2025-12-16, 1404/09/25**
Update count: **0**

Registration date
2025-12-16, 1404/09/25

Registrant information

Name
Marziyeh Kashian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3336 4334

Email address
marziye.kashian@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-02-20, 1404/12/01

Expected recruitment end date
2028-02-20, 1406/12/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tele-palliative care on hope and fear of disease progression in Gastrointestinal cancer patients: A parallel randomized clinical trial

Public title

The effect of tele-palliative care on hope and fear of disease progression in Gastrointestinal cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patient's age should be between 20 and 60 years old. The patient has a confirmed diagnosis of gastrointestinal cancer at stage II or III. Must be able to read and write. The patient must have a smartphone equipped with WhatsApp software on their mobile phone. Has undergone at least one chemotherapy session.

Exclusion criteria:

Having severe mental disorders (diagnosed and confirmed by a physician). Taking neuroleptic medications. Having a serious physical condition caused by cancer. Having uncorrectable vision and hearing impairments. Participation in any palliative care program during the course of the illness.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, the researcher will select participants from the research environment by referring to the research environment and finding eligible individuals based on inclusion and exclusion criteria. Then, an individual outside the research team, considering the order of entry of individuals into the study, will assign the patient to one of the two groups, palliative care intervention or the control group, using an allocation sequence concealed in white envelopes. The method of concealing the sequence is the use of white envelopes, which will be prepared in 74 numbers, and each sequence will be placed inside a white envelope, and the envelopes will be numbered.

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 Shahroud University of Medical Sciences

Street address

Haft Tir Square

City

Shahroud

Province

Semnan

Postal code

3614773943

Approval date

2025-11-15, 1404/08/24

Ethics committee reference number

IR.SHMU.REC.1404.113

Health conditions studied

1

Description of health condition studied

Gastrointestinal cancers

ICD-10 code

C15-C26

ICD-10 code description

Gastrointestinal cancers

Primary outcomes

1

Description

Hope in Gastrointestinal cancer Patients

Timepoint

Before the start of the intervention, immediately and one month after the end of the intervention

Method of measurement

Hirsch Hope Index (HHI) Questionnaire

2

Description

Fear of disease progression in Gastrointestinal Cancer Patients

Timepoint

Before the start of the intervention, immediately and one month after the end of the intervention

Method of measurement

Fear of Disease Progression Questionnaire (FoP-Q-SF)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants will receive palliative care intervention in the WhatsApp software environment. Each session will last 30 to 45 minutes, and one session per week will be held for participants for 6 weeks. In each session, the content of the sessions will be provided to the participants in the form of educational clips.
Category
Treatment - Other

2

Description
Control group: Participants will receive the same routine treatments and care they received before participating in the study, and at the end of the intervention for the experimental group and after the completion of data collection, the research intervention will also be shared with the control group.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital of Shahroud
Full name of responsible person
Dr. Hossein Bagheri
Street address
End of Imam Street
City
Shahroud
Province
Semnan
Postal code
۳۶۱۶۹۵۱۸۳۵
Phone
+98 23 3234 2000
Email
bagheri@shmu.ac.ir

2

Recruitment center
Name of recruitment center
Semnan Kowsar Hospital
Full name of responsible person
Dr. Hossein Bagheri
Street address
Golestan town
City
Shahroud
Province
Semnan
Postal code
9955835198
Phone
+98 23 3142 0000
Email
bagheri@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Hossein Ebrahimi
Street address
Haft Tir Square, Shahroud University of Medical Sciences
City
Shahroud
Province
Semnan
Postal code
361473947
Phone
+98 23 3239 5054
Email
vcr@shmu.a.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Hossein Bagheri
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work

Nursery

Street address
Haft Tir Square, Shahroud University of Medical Sciences

City
Shahroud

Province
Semnan

Postal code
3614773943

Phone
+98 23 3239 5054

Email
bagheri@shmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Dr. Hossein Bagheri

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Haft Tir Square, Shahroud University of Medical Sciences

City
Shahroud

Province
Semnan

Postal code
3614773943

Phone
+98 23 3239 5054

Email
bagheri@shmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Dr. Hossein Bagheri

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Haft Tir Square, Shahroud University of Medical Sciences

City
Shahroud

Province
Semnan

Postal code
3614773943

Phone
+98 23 3239 5054

Email
bagheri@shmu.ac.ir

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

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