

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

The effect of self care video education on quality of life and anxiety in Upper gastrointestinal cancer patients undergoing chemotherapy

Protocol summary

Study aim

Determining the effect of Self-care video education on quality of life and anxiety in patients with upper gastrointestinal cancer undergoing chemotherapy

Design

Clinical trials with intervention group and control group, parallel groups without blindness, randomized

Settings and conduct

The research environment of this study is the chemotherapy clinics of Shariati Hospital and the Institute cancer of Imam Khomeini Hospital. In this way, the samples are randomly assigned to the intervention and control groups using random numbers table from both hospitals. After performing the sampling and completing the QLQc30 quality of life questionnaire and the Spielberger's anxiety questionnaire, the educational film intervention group and the booklet control group are provided for viewing at home. Then, anxiety questionnaire is completed weekly for 3 months and the quality of life questionnaire is completed 3 months later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 18 years old Having cancer of upper gastrointestinal tract, according to a doctor's diagnosis Having experience at least one chemotherapy session Having a device to watch educational video Having the ability to read and write Full knowledge and understanding in Farsi Possibility to make phone calls and contacts with the patient Exclusion criteria: There is a diagnosis of psychological illness Use of anxiolytic drugs Vision and hearing problems

Intervention groups

The intervention group: includes 33 patient , educational film whose content includes: explanation of the disease, chemotherapy and its complications, and strategies for coping with illness and chemotherapy, relaxation techniques for reducing anxiety, to see them at home It will be given . Control group: Includes 33 patients, who are given a booklet.

Main outcome variables

Quality of Life anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181115041669N1**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **prospective**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

Registration date

2019-03-10, 1397/12/19

Registrant information

Name

shima kohansal

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3448 1541

Email address

shimakohansal@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-07-11, 1398/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of self care video education on quality of life and anxiety in Upper gastrointestinal cancer patients undergoing chemotherapy

Public title
The effect of self care video education on quality of life and anxiety in Upper gastrointestinal cancer patients undergoing chemotherapy

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
At least 18 years old Having cancer of upper gastrointestinal tract, according to a doctor's diagnosis Having experience at least one chemotherapy session Having a device to watch educational video Having the ability to read and write Full knowledge and understanding in Farsi Possibility to make phone calls and contacts with the patient
Exclusion criteria:
There is a diagnosis of psychological illness Use of anxiolytic drugs Vision and hearing problems lead to a lack of understanding educational content

Age
From **18 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
At first, the samples were selected by available sampling method and then randomly divided into control and experimental groups using a random number table.

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
Research Ethics Committee of Tehran University of

Medical Sciences
Street address
Sixth Floor., Central Organization of the University., Qods St., Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2018-12-19, 1397/09/28
Ethics committee reference number
IR.TUMS.FNM.REC.1397.167

Health conditions studied

1

Description of health condition studied
esophageal cancer
ICD-10 code
C15
ICD-10 code description
Malignant neoplasm of oesophagus

2

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
Measuring quality of life at baseline (pre-intervention) and 3 months after the start of education
Method of measurement
QLQ-C30 quality of life questionnaire

2

Description
Anxiety
Timepoint
Measurement of anxiety at the beginning of the study (before the intervention) and weekly for 3 months after intervention
Method of measurement
Spilburg's State Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group of educational films consists of animated slides with sound that include: description of the disease, chemotherapy and its complications, and strategies for coping with complications during illness and chemotherapy, relaxation techniques for reducing anxiety, this People are given a home for viewing.

Category

Rehabilitation

2

Description

Control group: This booklet is given to the group, as well as the educational content of the film, for viewing at home.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Shima kohansal

Street address

Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy, Tehran, Iran

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1411713135

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Fax

Email

shariatihosp@tums.ac.ir

Web page address

<http://shariati.tums.ac.ir>

2

Recruitment center

Name of recruitment center

Cancer Institute of imam khomeini hospital

Full name of responsible person

Shima kohansal

Street address

Cancer Institute Central 2, Dr. Gharib St, Keshavarz Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraeian

Street address

Research and Technology Department., 6th floor., Central University of the University., Quds St., Keshavarz Blvd

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itcenter@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shima kohansal

Position

MS nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery., Dr Mirkhani St.,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fariba Tabari

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Shima kohansal

Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

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