

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### evaluation of educational programs based on extended parallel process model (EPPM) in the field of esophageal cancer prevention behaviors among esophageal cancer patients' first-degree relatives with mix method

#### Protocol summary

##### Study aim

Determination of the effect of educational program on the perceived sensitivity, perceived severity, and self-efficacy of preventive behaviors in the field of self-care of esophageal cancer.

##### Design

The study , the relatives of patients with esophageal cancer using the random sampling method will be in two groups. only the intervention group will have an educational program, but in the control group there will be no intervention-based education. Finally, after 2 months of intervention, post-test is done in two groups.

##### Settings and conduct

In order to facilitate finding a patient, a study will be done in health centers and chemotherapy centers of hospitals in Golestan province. The study will be conducted with a descriptive phase to examine the target group's behaviors. Then the designed educational content will be available to the intervention group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Involvement of a family member in esophageal cancer and being alive or Has died at least 2 years ago, First-degree relatives of cancer patients (father, mother, sister, brother, children), Age between 60-30 years, Lack of problems and mental illness, Have at least reading and writing education Exclusion criteria: Do not want to cooperate, Be the patient's death for more than 2 years

##### Intervention groups

In the intervention group, training on the prevention of esophageal cancer behaviors will be done according to the preferred methods that individuals themselves suggest in the qualitative stage. But in the control group, there is no intervention based on education

##### Main outcome variables

The effect of education on Esophageal Cancer intention

and Prevention Behaviors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180725040588N1**

Registration date: **2018-10-02, 1397/07/10**

Registration timing: **prospective**

Last update: **2018-10-02, 1397/07/10**

Update count: **0**

##### Registration date

2018-10-02, 1397/07/10

##### Registrant information

##### Name

sakineh gerayllo

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3520 0417

##### Email address

gerayllo65@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

evaluation of educational programs based on extended parallel process model (EPPM) in the field of esophageal cancer prevention behaviors among esophageal cancer patients' first-degree relatives with mix method

**Public title**

The Impact of educational on esophageal cancer prevention behaviors

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

suffering one of the family members to esophageal cancer Having no problems and mental illness Have at least reading and writing education

**Exclusion criteria:**

Be the patient's death for more than 2 years Do not tend to interfere

**Age**

From **30 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple random The target group will be divided into two intervention and control groups with using the table of random numbers.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

People entering the study are divided into two groups and only the intervention group will be trained. However, behavioral assessment in both groups will be measured and compared before and after intervention.

**Secondary Ids**

empty

**Ethics committees****1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Sciences Yazd

**Street address**

Alam Square - Campus of Yazd Shahid Sadoughi University of Medical Sciences

**City**

yazd

**Province**

Yazd

**Postal code**

8915173160

**Approval date**

2017-11-26, 1396/09/05

**Ethics committee reference number**

IR.SSU.SPH.REC.1396.125

**Health conditions studied****1****Description of health condition studied**

esophageal cancer

**ICD-10 code**

C15

**ICD-10 code description**

Malignant neoplasm of oesophagus

**Primary outcomes****1****Description**

Prevention behaviors score in the questionnaire

**Timepoint**

2 months after the Educational intervention

**Method of measurement**

Self-report

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group:Relatives of patients with esophageal cancer- Educational Content on esophageal cancer prevention behaviors will be given to Intervening people

**Category**

Behavior

**2****Description**

Control group: Relatives of patients with esophageal cancer- The control group does not receive any training

**Category**

Behavior

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

مراکز شیمی درمانی در بیمارستان های استان گلستان

**Full name of responsible person**

sakineh gerayllo

**Street address**

Golestan - 5 Azar Avenue - facing the blood transfusion organization

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4981168318

**Phone**

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**Email**

gerayllo65@yahoo.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Masoud Mirzaei

**Street address**

Bahonar Square - Headquarters of Shahid Sadoughi University of Medical Sciences and Health Services Yazd - Third Floor

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+98 35 3726 3733

**Email**

Mmirzaei@ssu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

sakineh gerayllo

**Position**

Ph.D. student

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

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Imam Khomeini street. first alley

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Latest degree**

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**Other areas of specialty/work**

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**Province**

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**Postal code**

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**Phone**

+98 35 3820 9100

**Email**

gerayllo65@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

**Title and more details about the data/document**

The results will be published as an article in the research  
journals

**When the data will become available and for how  
long**

In the next 2 years

**To whom data/document is available**

Only people who ask for information the main  
investigator

**Under which criteria data/document could be used**

With the permission as a written or oral request

**From where data/document is obtainable**

School of Public Health. Shahid Sadoughi University of  
Medical Sciences Yazd

**What processes are involved for a request to access  
data/document**

With written request, they can access the library of Yazd  
University of Medical Sciences

**Comments**