

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### The Effect of Telephone Counseling and Education on Caregiver Strain and Unmet Needs in Family Caregivers and Self-care Behaviors of Patients with Cancer

#### Protocol summary

##### Study aim

Determination The Effect of Telephone Counseling and Education on Caregiver Strain and Unmet Needs in Family Caregivers and Self-care Behaviors of Patients with Cancer

##### Design

Clinical trials with control group, randomized, with parallel groups, without blinding

##### Settings and conduct

In two health Education clinics of Ghaem and Omid Hospital in Mashhad, 60 Caregivers and patients (in pairs) are randomly divided into two groups of control and intervention. Before intervention, demographic information and Caregiver Strain questionnaires and Unmet needs are completed by Caregivers and demographic information questionnaires and self-care behaviors are completed by patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria patients: willingness to participate in the study and informed consent, The definitive diagnosis of cancer of the esophagus and stomach and colorectal, Age greater than 18 and less than 65 years, The ability to read and write in Persian, Lack of speech and hearing problems, Candidate of Therapy 3 chemotherapy courses, Having access to the phone, Not a member health team, Lack of support by advocacy group, The main caregiver of being patient, The absence of specific psychological problems in carers and the use of medication to treat it; Unwillingness to continue cooperation

##### Intervention groups

In the intervention and control group, a 20-minute face-to-face training session is scheduled for caregivers of cancer patients. During this meeting, will be explained on how to care for the patient and At the end of the meeting, will be given several educational pamphlets include the materials taught to caregivers. In addition to

face-to-face training and educational pamphlets, the intervention group will receive four telephone consultations within 2 months (three courses of chemotherapy).

##### Main outcome variables

Caregiver Strain, Unmet Needs, Self-care Behaviors

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181114041660N1**

Registration date: **2018-11-24, 1397/09/03**

Registration timing: **prospective**

Last update: **2018-11-24, 1397/09/03**

Update count: **0**

##### Registration date

2018-11-24, 1397/09/03

##### Registrant information

##### Name

fatemeh ghorbani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3523 8858

##### Email address

ghorbanif941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-06-21, 1398/03/31

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The Effect of Telephone Counseling and Education on Caregiver Strain and Unmet Needs in Family Caregivers and Self-care Behaviors of Patients with Cancer

**Public title**  
The Effect of Telephone Counseling and Education on Caregiver Strain and Unmet Needs in Family Caregivers and Self-care Behaviors of Patients with Cancer

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Inclusion criteria patients: willingness to participate in the study and informed consent The definitive diagnosis of cancer of the esophagus and stomach and colorectal Age greater than 18 and less than 65 years The ability to read and write in Persian Lack of speech and hearing problems Candidate of Therapy 3 chemotherapy courses Having access to the phone Not a member health team Lack of support by advocacy group Inclusion criteria caregivers: willingness to participate in the study and informed consent The main caregiver of being patient The ability to read and write in Persian Having access to the phone Lack of speech and hearing problems The absence of specific psychological problems and the use of medication to treat it Not a member health team Lack of support by advocacy group  
**Exclusion criteria:**  
 Unwillingness to continue cooperation Failure to answer telephone calls and disconnect (if He/She does not answer 3 phone calls) The occurrence of stressful events for carers and patients during an intervention such as divorce, death of close relatives, sick death and job loss Failure to fully complete all three questionnaire of the self-care patients by the patients and the Burden and Unmet needs by the caregivers The patient's inappropriate general condition during the intervention so that his continued cooperation is not feasible Caregiver support by support groups

**Age**  
From **18 years** old to **65 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**  
Block.Put the Four blocks in a sealed envelope and Then

they will be arranged in a straightforward Lottery way.

**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

The Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Ebne sina St, Mashhad Nursing and Midwifery Faculty

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913199

#### Approval date

2018-10-16, 1397/07/24

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1397.056

## Health conditions studied

### 1

#### Description of health condition studied

Esophagus Cancer

#### ICD-10 code

C15

#### ICD-10 code description

Malignant neoplasm of esophagus

### 2

#### Description of health condition studied

Stomach Cancer

#### ICD-10 code

C16

#### ICD-10 code description

Malignant neoplasm of stomach

### 3

#### Description of health condition studied

Colon Cancer

#### ICD-10 code

C18

#### ICD-10 code description

Malignant neoplasm of colon

#### 4

##### **Description of health condition studied**

Colon Cancer

##### **ICD-10 code**

C19

##### **ICD-10 code description**

Malignant neoplasm of rectosigmoid junction

#### 5

##### **Description of health condition studied**

Rectum Cancer

##### **ICD-10 code**

C20

##### **ICD-10 code description**

Malignant neoplasm of rectum

#### 6

##### **Description of health condition studied**

Rectum Cancer

##### **ICD-10 code**

C21

##### **ICD-10 code description**

Malignant neoplasm of anus and anal canal

## **Primary outcomes**

#### 1

##### **Description**

Caregiver Strain

##### **Timepoint**

Before the intervention and at the end of the intervention (the end of the second month)

##### **Method of measurement**

Zarit caregiver Burden Inventory

#### 2

##### **Description**

unmet needs

##### **Timepoint**

Before the intervention and at the end of the intervention (the end of the second month)

##### **Method of measurement**

Supportive Care Needs Survey Partners and Caregivers

#### 3

##### **Description**

self-care behaviors

##### **Timepoint**

Before the intervention and at the end of the intervention (the end of the second month)

##### **Method of measurement**

Nail Self-care Dairy questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

#### 1

##### **Description**

Intervention group: In the intervention group, a 20-minute face-to-face training session will be provided to caregivers of cancer patients. During this meeting, will be briefly explained on how to care for the patient, nutrition, activity and rest, the prevention of infection and the management of the symptoms of the disease and the side effects of chemotherapy and at the end of the meeting several educational pamphlets includes subjects taught will be given to carers. In addition to face-to-face training and educational pamphlets, the intervention group will receive four telephone consultations within 2 months (in the first course of chemotherapy after entering the study 2 calls and in the second and third chemotherapy course each one will receive a call). In the first telephone interview, a review of educational materials about patient problems and self-care with the patient is conducted and the second session will be discussed with the caregiver about symptoms management, Uncertainty reduction, optimistic attitudes and effective adjustment skills.

##### **Category**

Other

#### 2

##### **Description**

Control group: In the control group, a 20-minute face-to-face training session will be provided to caregivers of cancer patients. During this meeting, will be briefly explained on how to care for the patient, nutrition, activity and rest, the prevention of infection and the management of the symptoms of the disease and the side effects of chemotherapy and at the end of the meeting several educational pamphlets includes subjects taught will be given to carers. Carers will receive routine education through nurses and referral to hospital health Education clinics.

##### **Category**

Other

## **Recruitment centers**

#### 1

##### **Recruitment center**

##### **Name of recruitment center**

Ghaem hospital

##### **Full name of responsible person**

Ghorbani Fatemeh

##### **Street address**

Dr. Ali Shariati Square, Beginning at Ahmadabad Street

##### **City**

Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9176699199  
**Phone**  
+98 51 3840 0000  
**Email**  
ghorbanif941@mums.ac.ir

## 2

### **Recruitment center**

**Name of recruitment center**  
Omid hospital  
**Full name of responsible person**  
Ghorbani Fatemeh  
**Street address**  
koohsangi Ave, Alndasht Square  
**City**  
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9176613775  
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Ghorbanif941@mums.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Tafaghodi Mohsen  
**Street address**  
University St, Facing University Street 18, Deputy of  
University Technology and Research  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
917751365  
**Phone**  
+98 51 3841 2081  
**Email**  
tafaghodim@mums.ac.ir

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Mashhad 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**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Ghorbani Fatemeh  
**Position**  
Nursing Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Mashhad, Ebme sina St, Nursing and Midwifery  
Faculty  
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**Postal code**  
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**Phone**  
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**Email**  
ghorbanif941@mums.ac.ir

## **Person responsible for scientific inquiries**

### **Contact**

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Zare Masoud  
**Position**  
tutor  
**Latest degree**  
Master  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Ghorbani Fatemeh

**Position**

Nursing Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Email**

ghorbanif941@mums.ac.ir

## 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 total potential data can be shared after unidentifiable people

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

Start the access period 6 months after printing the results

**To whom data/document is available**

Only for researchers working in academic and scientific institutions

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

The data can be used for other human research and health centers

**From where data/document is obtainable**

Library of the School of Nursing and Midwifery of Mashhad ghorbanif941@mums.ac.ir

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

Visit the Library of Nursing and Midwifery Faculty of Mashhad

**Comments**