

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Aug 2026

**The effectiveness of the intervention of using a mobile educational application on the burden of complications caused by chemotherapy and the care burden of elderly caregivers with gastrointestinal cancer compared to the conventional method.**

### Protocol summary

#### Study aim

Determining the effect of mobile-based educational program on the complications of chemotherapy in the elderly undergoing chemotherapy and the care burden of caregivers

#### Design

The clinical trial has a control and intervention group with parallel groups and is not blinded and randomized and has a sample size of 90 patients and spss software was used for randomization.

#### Settings and conduct

This research was conducted in Omid and Imam Reza Hospital and Reza Medical Center of Mashhad, and the control group and intervention group are from one center and the other two centers. Then they will be given the demographic characteristics and questionnaires of Zarit's care burden and Anderson's burden of complications, and the application will be installed on the patient's caregivers' mobile phones, they will receive the necessary training based on the experienced complication, and the control group will receive only conventional training. And after the completion of the research, this software will be provided to the control group, and the second round of filling the questionnaires will be after the completion of the fourth session of chemotherapy, and the third round will be one month after the completion of the fourth session of chemotherapy.

#### Participants/Inclusion and exclusion criteria

Diagnosis of chemotherapy; non-metastatic cancer; Gastrointestinal cancer; Age over 60 years; Starting the second course of chemotherapy; Exclusion criteria: Disaffiliation; The death of an elderly person.

#### Intervention groups

In the intervention group, in addition to face-to-face training, an educational application is installed on the

mobile phones of their caregivers. In the control group, the same educational content will be given through face-to-face teaching method.

#### Main outcome variables

The amount of care burden of the patient and the amount of complications of chemotherapy for the elderly

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20201205049613N1**

Registration date: **2022-10-02, 1401/07/10**

Registration timing: **retrospective**

Last update: **2022-10-02, 1401/07/10**

Update count: **0**

#### Registration date

2022-10-02, 1401/07/10

#### Registrant information

##### Name

Malihe Khalilnia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3821 1545

##### Email address

khalilniam2@mums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-05-05, 1400/02/15  
**Expected recruitment end date**  
 2021-08-06, 1400/05/15  
**Actual recruitment start date**  
 2021-05-05, 1400/02/15  
**Actual recruitment end date**  
 2021-08-06, 1400/05/15  
**Trial completion date**  
 2021-08-06, 1400/05/15

**Scientific title**  
 The effectiveness of the intervention of using a mobile educational application on the burden of complications caused by chemotherapy and the care burden of elderly caregivers with gastrointestinal cancer compared to the conventional method.

**Public title**  
 Investigating the effectiveness of using a mobile phone educational application on the elderly with gastrointestinal cancer

**Purpose**  
 Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Diagnosis of chemotherapy for the patient Individual or combination therapy No history of surgery Non-metastatic cancer No vision or hearing problems Not receiving previous training Gastrointestinal cancer (stomach, esophagus, colon, which does not have an ostomy) Age over 60 years Start of the second course of chemotherapy Having physical ability and consciousness  
**Exclusion criteria:**  
 Not having an Android mobile phone available Lack of literacy Unwillingness to participate in research

**Age**  
 From **60 years** old

**Gender**  
 Both

**Phase**  
 N/A

**Groups that have been masked**  
*No information*

**Sample size**  
 Target sample size: **90**  
 Actual sample size reached: **90**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**  
 In a simple way, people are divided into two groups by SPSS software. This sequence is kept in a sealed envelope. After confirming the entry criteria for each of the research units, the researcher will open the door of the envelope and will determine change his group based on this sequence. This procedure will continue until the completion of the people of both research groups.

**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

School of Nursing and Midwifery - Mashhad University of Medical Sciences

##### Street address

Faculty of Nursing and Midwifery, Doctor's Crossroad, Ibn Sina Street, University Street, Khorasan Razavi

##### City

مشهد

##### Province

Razavi Khorasan

##### Postal code

9137913199

#### Approval date

2021-02-20, 1399/12/02

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1399.090

## Health conditions studied

### 1

#### Description of health condition studied

Gastrointestinal (stomach) cancer

#### ICD-10 code

C16

#### ICD-10 code description

Malignant neoplasm of stomach

### 2

#### Description of health condition studied

Gastrointestinal cancer (esophagus)

#### ICD-10 code

C15

#### ICD-10 code description

Malignant neoplasm of oesophagus

### 3

#### Description of health condition studied

Gastrointestinal cancer (colon)

#### ICD-10 code

C18

#### ICD-10 code description

Malignant neoplasm of colon

## Primary outcomes

## 1

### Description

Care burden of elderly caregivers undergoing chemotherapy

### Timepoint

In three cases, the first time before the start of the second round of chemotherapy, the second time after the end of the fourth course of chemotherapy and the third time one month after the fourth session of chemotherapy, the first and second rounds of primary outcomes are measured and the third round of outcomes Secondary is measured

### Method of measurement

Using specific questionnaires

## 2

### Description

The burden of complications in the elderly undergoing chemotherapy

### Timepoint

In three cases, the first time before the start of the second round of chemotherapy, the second time after the end of the fourth course of chemotherapy and the third time one month after the fourth session of chemotherapy, the first and second rounds of primary outcomes are measured and the third round of outcomes Secondary is measured

### Method of measurement

Using specific questionnaires

## Secondary outcomes

empty

## Intervention groups

## 1

### Description

Intervention group: In addition to face-to-face training, a mobile phone-based training program will be installed and trained on caregivers' mobile phones.

### Category

Other

## 2

### Description

Face-to-face training by nurses and educational pamphlets by the researcher

### Category

Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Reza Hospital (AS) and Omid Hospital and Reza Chemotherapy Center (Qasimabad)

### Full name of responsible person

Research assistant of the organization

### Street address

Faculty of Nursing and Midwifery, Doctor's Crossroad, Ibn Sina Street, University Street, Khorasan Razavi

### City

Mashhad

### Province

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### Postal code

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### Phone

+98 51 3859 1511

### Email

NAMResearch@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Research assistant of the organization

#### Street address

Faculty of Nursing and Midwifery, Doctor's Crossroad, Ibn Sina Street, University Street, Khorasan Razavi

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### 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**

Najmeh Valizadeh Zare

**Position**

Faculty of Mashhad University of Medical Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Najmeh Valizadeh Zare

**Position**

Faculty of Mashhad University of Medical Sciences

**Latest degree**

Ph.D.

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**Email**

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

Mashhad University of Medical Sciences

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

Can be shared after identifying people

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

Access since 1401

**To whom data/document is available**

Researchers working in academic and scientific institutions

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

Researchers working in academic and scientific institutions

**From where data/document is obtainable**

najme valizade zare-nvalizade zare@mums.ac.ir

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

The applicant will send an email to the person in charge of the project and it will be sent after reviewing the information.

**Comments**