

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### "Effect of education via educational SMS(short message sending) on self care and quality of life in cancer patients"

#### Protocol summary

##### Study aim

Determining the effect of SMS on self-care and quality of life of cancer patients

##### Design

Participants were divided into two groups of interventions (A) and control(B) through block randomized allocation.

##### Settings and conduct

Participants in control group will complete demographic, self care knowledge and behavior, and quality of life questionnaires and receive routine care. Participants in intervention group will complete all questionnaires, and in addition to receive routine care, will receive text messages about nutrition, increasing hope, decreasing anxiety, depression, fatigue and nausea, prevention of infection and bleeding, prevention and care of mucositis, and the importance of regular visits and follow up, for one month. Then the data collection will be performed in two more stages in both groups two weeks and one month after starting the study. The data will be analyzed. The research environment will be Ayatollah Khansari Hospital. .

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-45 years, having a mobile phone with the ability to receive text message, having the ability to read, individuals with gastrointestinal cancer without metastasis, chemotherapy will be continue at least one month after the start of the study. Exclusion criteria: If the patient died during the intervention, unable to continue participation in the study due to acute complications of cancer and its treatments, increasing the severity of the disease in the patient.

##### Intervention groups

Intervention group, in addition to routine care, will receive messages about nutrition, increasing hope, decreasing anxiety and depression and self care for one month.

##### Main outcome variables

Self-care behaviors and quality of life

#### General information

##### Reason for update

##### Acronym

ندارد

##### IRCT registration information

IRCT registration number: **IRCT20121016011136N4**

Registration date: **2018-05-27, 1397/03/06**

Registration timing: **retrospective**

Last update: **2018-05-27, 1397/03/06**

Update count: **0**

##### Registration date

2018-05-27, 1397/03/06

##### Registrant information

##### Name

pegah Matoury

##### Name of organization / entity

Tarbat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 2524 5616

##### Email address

pegah.matoury@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2017-07-23, 1396/05/01

##### Actual recruitment start date

2017-04-21, 1396/02/01

##### Actual recruitment end date

2017-07-23, 1396/05/01  
**Trial completion date**  
empty

**Scientific title**  
"Effect of education via educational SMS(short message sending) on self care and quality of life in cancer patients"

**Public title**  
"Effect of education via educational SMS(short message sending) on self care and quality of life in cancer patients under chemotherapy"

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients aged 18-45 years Having a mobile phone with the ability to receive text message Having the ability to read . Individuals with gastrointestinal cancer without metastasis. Chemotherapy will be continue at least one month after the start of the study.  
**Exclusion criteria:**  
If the patient died during the intervention. Unable to continue participation in the study due to acute complications of cancer and its treatments. Increasing the severity of the disease in the patient.

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**  
Target sample size: **45**  
Actual sample size reached: **45**

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

**Randomization description**  
Participants were divided into two groups of interventions (A) and control(B) through block randomized allocation. Using a block size of four (12 blocks by using a computer program) for two groups (A and B) leads to six possible arrangements: AABB BBAA ABAB BABA ABBA BAAB... and then these blocks are randomly sorted and individuals will be placed in two groups of intervention and control .

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The person who analyze the data of the study and patients do not know about the allocation in the intervention and control groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Arak University of Medical Sciences

##### Street address

Basij Square, Pardis complex

##### City

Arak

##### Province

Markazi

##### Postal code

8634173639

#### Approval date

2016-04-28, 1395/02/09

#### Ethics committee reference number

lr.arakmu.rec.1394.269

## Health conditions studied

### 1

#### Description of health condition studied

cancer

#### ICD-10 code

C00-D48

#### ICD-10 code description

malignant neoplasm of GI tract

## Primary outcomes

### 1

#### Description

self care

#### Timepoint

Two weeks and one month after starting the study

#### Method of measurement

self care questionnaire

### 2

#### Description

Quality of life

#### Timepoint

Two weeks and one month after starting the study

#### Method of measurement

Quality of life questionnaire for cancer patients

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Participants in intervention group will complete all questionnaires, and in addition to receive routine care, will receive text messages about nutrition, increasing hope, decreasing anxiety, depression, fatigue and nausea, prevention of infection and bleeding, prevention and care of mucositis, and the importance of regular visits and follow up, for one month.

#### Category

Lifestyle

### 2

#### Description

Participants in control group will complete demographic, self care knowledge and behavior, and quality of life questionnaires and receive routine care

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Khansari Hospital

##### Full name of responsible person

Behbood Amiri

##### Street address

Daneshgah street

##### City

Arak

##### Province

Markazi

##### Postal code

0098 93 311602

##### Phone

+98 86 3417 3503

##### Fax

+98 86 3417 3505

##### Email

Behbodamiri@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Mohammad Arjomandzadegan

##### Street address

Basij Square, Pardis Complex

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3417 3645

##### Fax

+98 86 3417 3645

##### Email

arjomandzadegan@arakmu.ac.ir

##### Web page address

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Arak 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

Zeinab Alizadeh

##### Position

PhD student

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

No.18, Rahimi Ave, Ghandi street

##### City

Tehran

##### Province

Tehran

##### Postal code

5344151159

##### Phone

+98 914 323 7870

##### Email

zeinab\_alizadeh88@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Zeinab Alizadeh

**Position**

PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

No.18, Rahimi Ave., Ghandi street

**City**

Tehran

**Province**

Tehran

**Postal code**

5344112159

**Phone**

+98 914 323 7870

**Email**

zeinab\_alizadeh88@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zeinab Alizadeh

**Position**

PhD student in nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

No.18,Rahimi Ave,Ghandi street

**City**

Tehran

**Province**

Tehran

**Postal code**

5344132159

**Phone**

+98 935 651 2981

**Email**

zeinab\_alizadeh88@yahoo.com

**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**

Not applicable

**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**

Not applicable

**Data Dictionary**

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