

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jul 2026

### Effect of Peer support, Remote, on subjective well-being in patients with colorectal cancer

#### Protocol summary

##### Study aim

Determining the effect of Peer support, Remote, on subjective well-being in patients with colorectal cancer

##### Design

A randomized clinical trial, with control and intervention groups, with parallel design, superiority, randomly divided to two groups of intervention and control (using a random number table using [www.randomization.com](http://www.randomization.com)). Sample size will be determined by Pilot study.

##### Settings and conduct

After referral to Mashhad's Oncology units, will be completed at the same meeting, pre-test (subjective well-being questionnaire) by Qualified available patients. At the same meeting, patients with peer criterias, as peer, will be selected. Then at the same meeting, the work process is explained to the peers, and the other patients are placed in randomized assignment in two groups of intervention and control. Patients undergoing intervention, After the introduction of the phone, with peer, will be supported by peer for one month, at least twice a week by telephone, and three times a week by the Internet. One month after the end of the intervention, the post-test is performed for two groups. This study will be single blind, analyst will be unaware of the groups of intervention and control and the data collected and which data will be relevant to which group.

##### Participants/Inclusion and exclusion criteria

People who have colorectal cancer can enter the study.  
People who do not have colorectal cancer can not enter the study.

##### Intervention groups

Both groups will be the same for everyone, and the routine self-care checklist is routinely given to both groups. Only the intervention group, under peer support intervention, is placed at least twice a week by phone and at least three times a week by the Internet (virtual network), for one month. There is no intervention in the control group.

##### Main outcome variables

Increasing subjective well-being

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190123042480N1**

Registration date: **2019-03-28, 1398/01/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-28, 1398/01/08**

Update count: **0**

##### Registration date

2019-03-28, 1398/01/08

##### Registrant information

##### Name

Mahla Rahimi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3762 9367

##### Email address

rahimim941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-04, 1397/11/15

##### Expected recruitment end date

2019-04-04, 1398/01/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Effect of Peer support, Remote, on subjective well-being in patients with colorectal cancer

### Public title

Effect of Peer support, Remote, on subjective well-being in patients with colorectal cancer

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

People over the age of 18, who have colorectal cancer based on cytological diagnostic findings and an oncologist's confirmation. does not have severe cognitive impairment (his Psychological examination score is greater than 22 of 30). Have literacy reading and writing. Have audiovisual health (ability to hear and see even with auxiliary equipment). Give the phone number to calling. Have the ability to use smartphone and internet (virtual network). Have the ability to communicate verbally and non verbally. The peer also must, in addition to the research unit criteria, have a score of at least 40, from the Warwick-Edinburgh Subjective Welfare Questionnaire, and successfully completed the treatment.

#### Exclusion criteria:

Patients with colorectal cancer, which have fistulas.

### Age

From **18 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Data analyser

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Patients are randomly assigned to two groups of intervention and control (using the random numbers table at [www.randomization.com](http://www.randomization.com)).

### Blinding (investigator's opinion)

Single blinded

### Blinding description

The analyst will be unaware of the intervention and control groups and the data collected and which group it relates to.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Deputy of Research and Technology University, Mashhad University of Medical Sciences, Opposite University Street 18, University Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

13944 - 91388

##### Approval date

2019-02-09, 1397/11/20

##### Ethics committee reference number

IR.MUMS.NURSE.REC.1397.076

## Health conditions studied

### 1

#### Description of health condition studied

Colorectal cancer

#### ICD-10 code

C18-20

#### ICD-10 code description

C18 Malignant neoplasm of colon. C19 Malignant neoplasm of rectosigmoid junction. C20 Malignant neoplasm of rectum

## Primary outcomes

### 1

#### Description

Subjective well-being Score, in the Warwick Edinburgh Questionnaire

#### Timepoint

Before the intervention and one month after the end of the intervention

#### Method of measurement

Warwick Edinburgh subjective well-being Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The intervention group is subjected to peer support interventions for one month, at least twice a week by phone, and at least weekly by the Internet (virtual network) at least once a week.

**Category**

Other

**2****Description**

The control group receives the same routine care and there is no intervention in it.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Omid Hospital

**Full name of responsible person**

Mahla Rahimi

**Street address**

Alandasht Square , Koohsangi Avenue

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176613775

**Phone**

+98 51 3842 6082

**Email**

omidhos@mums.ac.ir

**2****Recruitment center****Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Mahla Rahimi

**Street address**

Imam Reza Hospital, Imam Reza Hospital Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3854 3031

**Email**

emamreza@mums.ac.ir

**3****Recruitment center****Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Mahla Rahimi

**Street address**

Beginning at Ahmadabad Street, Dr. Ali Shariati Square,

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91766-99199

**Phone**

+98 51 3840 0000

**Email**

Quaem.Medical.Center@mums.ac.ir

**4****Recruitment center****Name of recruitment center**

Hashemi Nejad Hospital

**Full name of responsible person**

Mahla Rahimi

**Street address**

end of the Abu Rayhan Blvd, Shahid Mofatheh

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

99191 - 91778

**Phone**

+98 51 3273 7011

**Email**

p.relations@mums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Taphaghodi

**Street address**

Knowledge and Health City, In the end of Shahid Fakouri Blvd (In front of Fakouri 94), Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

99191 - 91778

**Phone**

+98 51 3879 5031

**Email**

p.relations@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

Razavi Khorasan

**Postal code**

46339 - 91976

**Phone**

+98 51 3762 9367

**Email**

rahimim941@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahla Rahimi

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 9, Majidi Ave 5., Janbaz Ave 9., Janbaz Blvd

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

46339 - 91976

**Phone**

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**Fax****Email**

rahimim941@mums.ac.ir

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**Postal code**

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rahimim941@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Mahla Rahimi

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 9, Majidi 5, Janbaz 9, Janbaz Blvd

**City**

Mashhad

**Province****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