

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). 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).

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

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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

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9137913316

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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,

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91766-99199

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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

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Razavi Khorasan

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99191 - 91778

Phone

+98 51 3273 7011

Email

p.relationships@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

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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

Razavi Khorasan

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46339 - 91976

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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

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Postal code

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rahimim941@mums.ac.ir

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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