

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The impact of a supportive program on family supportive care needs of patients with Colorectal Cancer

Protocol summary

Study aim

The impact of a supportive plan is determined on the family supportive care needs of people with Colon Cancer

Design

A randomized trial with intervention and control group, a sample size of 62 caregivers of patients with colon cancer who referred to Imam Khomeini Hospital in Sari and randomly assigned to one of the intervention or control groups

Settings and conduct

The supportive care needs questionnaire is completed at the time of admission and one month later by the participants. The content of the training sessions is based on the results of the research and is based on authoritative sources and books on colon cancer and approved by the oncology department of the university in the project implementation site.

Participants/Inclusion and exclusion criteria

Inclusion criteria are ages between 18 to 80 years, having a relation with the patient (suffering from colon cancer), playing a vital role in patient care, having a willingness to participate in the research. exclusion criteria are Death of the carer, Failure to complete the questionnaire, Patient death

Intervention groups

The intervention group, the family members of the colon cancer patients who will be trained in attendance at the training classes held by the organizers, will have two sessions of training for 1.5 hours, with a two-week interval, and the control group, under the typical training will be provided by health center personnel.

Main outcome variables

The primary outcome of supportive care needs for participants in both groups and the secondary outcomes of their supportive care needs is in different dimensions, which will be compared using the supportive care needs questionnaire (SCNS, P & C39) between the two groups.

General information

Reason for update

Acronym

CRC

IRCT registration information

IRCT registration number: **IRCT20171209037796N1**

Registration date: **2018-04-21, 1397/02/01**

Registration timing: **retrospective**

Last update: **2018-04-21, 1397/02/01**

Update count: **0**

Registration date

2018-04-21, 1397/02/01

Registrant information

Name

Maryam Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-04-19, 1397/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of a supportive program on family supportive care needs of patients with Colorectal Cancer

Public title

The impact of a supportive program on family supportive care needs of patients with Colorectal Cancer

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Have a relation with colon cancer patient . Physically and mentally, have the ability to participate in the study and complete the questionnaire Have willing to participate in the study Have a vital role in caring for the patient

Exclusion criteria:

Immigration or the death of the family caregiver during the study Absence in training sessions (two sessions) Failure to complete the research questionnaire Patient death

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Caregivers who have the conditions for participation in the study are included in the target (accessible or simple) sampling and will be randomly assigned as blocks in the intervention (A) and control (B) group. First, 15 blocks of four are defined as follows: ABAB, BBAA, BABA, BAAB, AAAB, ABBA, etc., and then these blocks are arranged randomly and individuals in A and B will be placed in two groups of intervention and control; this will continue until the sample size is completed. Family member A will be placed in the control group and B will be in the control group so that the sequence of samples will be random. After explaining the goals of the study and how the plan will be done for the patient and the family caring for them, oral consent will be given to them for participation in the study. Researchers will be assured that their information will be confidential and can be excluded at any time.

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**

Ethics Committee of Arak University of Medical Sciences

Street address

Basij Sq, Payambar Azam University complex, Emam Mosa Kazem building, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-02-09, 1396/11/20

Ethics committee reference number

IR.ARAKMU.REC.1396.24

Health conditions studied**1****Description of health condition studied**

Review the family supportive care needs of people with colon cancer

ICD-10 code

C-18 , C-2

ICD-10 code description

Malignant neoplasm of colon and rectum

Primary outcomes**1****Description**

supportive care needs

Timepoint

At the beginning of the study, one month after the intervention

Method of measurement

A Survey of Supporting Care Needs Assessment Questionnaire(SCNS P&C39)

2**Description**

Health system & information needs

Timepoint

At the beginning of the study, one month after the intervention

Method of measurement

Health system & information dimension of SCNS-P&C39

3**Description**

Psychological needs

Timepoint

At the beginning of the study, one month after the intervention

Method of measurement
Psychological dimension of SCNS-P&C39

4

Description

Job and social needs

Timepoint

At the beginning of the study, one month after the intervention

Method of measurement

Job and social dimension of SCNS-P&C39

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Family members of the colon cancer patients who will be trained in attendance at the training sessions organized by the presenter. The two-week training session will be held for 1.5 hours with a two-week interval, the contents of the protocols' training sessions are based on the results of the research and are based on authoritative references and books on colon cancer and approved by the Oncology Department of the University where the project was implemented. Also, answering the questions of patients in specialized medical fields will be done with an oncologist's consultation and the result will be announced to them.

Category

Other

2

Description

Control group: Family members of patients with colon cancer who undergo routine training provided by health center staff.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital, Sari

Full name of responsible person

Dr Ghasem Janabaei

Street address

Razi

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Mazandaran

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4816633131

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr.Mohammad Arjmandzadegan

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Basij Sq, Payambar Azam University complex, Emam Mosa Kazem building, Arak

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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

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

Arak University of Medical Sciences

Full name of responsible person

Seyedeh Maryam Hosseini Joveini

Position

Master Student in Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Full name of responsible person

Nazi Nejat

Position

Aistant Proffessor/Nursing Ph.D.

Latest degree

Ph.D.

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable