

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of education based on family-centered empowerment model versus no educational intervention on the self-care ability of patients with colorectal cancer

Protocol summary

Study aim

To determine the effect of education based on family-centered empowerment model on self-care ability of patients with colorectal cancer

Design

In this study, 72 eligible patients with colorectal cancer who refer to the Colorectal Clinic Surgery Department of Faghihi Hospital in Shiraz will be selected. The participants will be randomly allocated to experimental and control groups, and each will be assigned a code.

Settings and conduct

The study will be conducted in the colorectal cancer surgery department of Shahid Faghihi Hospital of Shiraz. The eligible patients will be randomly allocated to experimental and control groups. The experimental group members will receive 3 to 5 sessions of education based on family-centered empowerment model in groups of 5 through group discussions. During this time, members of the control group do not receive any special training. All participants will complete a researcher-made self-care ability assessment questionnaire before the intervention, immediately after the intervention, and one month after the end of the intervention.

Participants/Inclusion and exclusion criteria

Major inclusion criteria: A definite diagnosis of colorectal cancer according to the pathologic response of patients; age from 20 to 70 years; and the literacy to read and write. Major exclusion criteria: The impossibility for the presence of at least one member of the patient's family during training sessions and having difficulty with learning.

Intervention groups

Experimental group: They will receive 3 to 5 sessions of education based on family-centered empowerment model, which covers four stages: awareness and cognition, self-efficacy, self-esteem, and evaluation. Control group: The control group will not receive this

educational intervention.

Main outcome variables

self-care ability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180729040624N1**

Registration date: **2019-04-07, 1398/01/18**

Registration timing: **retrospective**

Last update: **2019-04-07, 1398/01/18**

Update count: **0**

Registration date

2019-04-07, 1398/01/18

Registrant information

Name

Hojat alah Nasri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5000

Email address

h.nasri2020@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-05, 1397/04/14

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education based on family-centered empowerment model versus no educational intervention on the self-care ability of patients with colorectal cancer

Public title

The effect of family-centered empowerment model on self-care ability

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Definite diagnosis of colorectal cancer according to the pathological response of patients
Age from 20 to 70 years
Informed consent for participation
Literacy to read and write
History of surgery

Exclusion criteria:

Problems with learning
Impossibility of the presence of at least one member of the patient's family in the training sessions

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be allocated into experimental and control groups using the table of random numbers.

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**

Birjand University of Medical Sciences

Street address

Ghafari Street

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2018-07-04, 1397/04/13

Ethics committee reference number

IR.BUMS.REC.1397.090

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

colorectal cancer

ICD-10 code

C18

ICD-10 code description

Malignant neoplasm of colon

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

self-care ability

Timepoint

before the intervention, immediately after the intervention, and one month after the end of the intervention

Method of measurement

researcher-made self-care ability assessment questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group (family-centered empowerment model): The members will receive 3 to 5 sessions of education based on family-centered empowerment model, which covers four stages: awareness and cognition, self-efficacy, self-esteem, and evaluation. Education will be delivered in groups of 5 using group discussion.

Category

Behavior

2**Description**

Control group: The control group will not receive a specific educational intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Faghihi Hospital of Shiraz

Full name of responsible person

Hojat alah Nasri

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Zand

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Hojatalah Nasri

Position

M.Sc. Student of Nursing

Latest degree

Bachelor

Other areas of specialty/work

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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

Not applicable

Title and more details about the data/document

Deidentified Individual Participant Data Set

When the data will become available and for how long

After the article extracted from the research project is published and for six months

To whom data/document is available

Readers of the article

Under which criteria data/document could be used

For research purposes only

From where data/document is obtainable

Via email sent to the corresponding author of the extracted paper (Dr Gholamhosain Mahmudirad: midwifery@bums.ac.ir)

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

Personal correspondence with the corresponding author of the article via email along with the provision of explanations concerning the research purposes and related evidence. A response will be made within a week.

Comments