Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of a care program based on Roy adaptation model of nursing on depression, anxiety and stress scores in colorectal cancer patients

Protocol summary

Study aim

Determination of the effect of care program based on the Roy adaptation pattern on the severity of depression, anxiety and stress in patients with colorectal cancer

Design

After obtaining written consent from the studied units, the pre-test was done by demographic form and the DASS-21 questionnaire was administered to both groups of control and intervention, and then to examine the maladaptive behaviors of the patients in the intervention group; Roy form and examination is used. After 2 months follow-up and advice and end all the stages of intervention,The Roy follow-up care model was used;; post-test was done in both control and intervention groups and finally, data analysis was performed

Settings and conduct

Patients with colorectal cancer at Urmia Imam Khomeini Hospital in two groups of control and intervention received routine and based on the Roy adaptation pattern nursing care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Definition of colorectal carcinoma of the third or fourth stage based on the patient's pathology. Have at least 3 months to diagnose the disease. Age of 18 to 60 years Ability to understand training Having the right physical and mental status to participate in the study; The desire to participate in the study, Lack of participation in previous care plans. Have at least literacy and writing The patient's lack of use of drugs to treat depression, anxiety and stress Non-underlying disease other than cancer that affects the patient's mental status. Exclusion criteria: Unwillingness to participate in the study The patient's death during the study period

Intervention groups

18 patients with colorectal cancer in intervention group received a nursing care based on Roy pattern. 18 patients with colorectal cancer in control group received usual nursing care.

Main outcome variables

depression, anxiety and stress in patients with colorectal cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160220026662N5**
Registration date: **2019-01-06, 1397/10/16**
Registration timing: **retrospective**

Last update: **2019-01-06, 1397/10/16**
Update count: **0**

Registration date

2019-01-06, 1397/10/16

Registrant information

Name

Nader Aghakhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3275 4816

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nader1453@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

2016-04-20, 1395/02/01

Actual recruitment end date

2016-08-10, 1395/05/20

Trial completion date

2016-08-10, 1395/05/20

Scientific title

The effect of a care program based on Roy adaptation model of nursing on depression, anxiety and stress scores in colorectal cancer patients

Public title

The effect of a care program based on Roy adaptation model of nursing in colorectal cancer patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Definition of being colorectal cancer in the third or fourth stage based on the patient's pathology At least 3 months have passed since diagnosis. Age of 18 to 60 years Ability to understand training Having the right physical and mental status to participate in the study The desire to participate in the study Not participating in previous care plans Have at least literacy and writing skill The patient does not use drugs to treat depression, anxiety and stress Lack of underlying illness other than cancer that affects the patient's mental status.

Exclusion criteria:

Unwilling to participate in the study The patient's death during the duration of the study

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **36**

Actual sample size reached: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocks randomization method was used to allocate individuals to groups

Blinding (investigator's opinion)

Single blinded

Blinding description

the allocation of patients to the groups was done by a nurse in the department that have no information about the treatment of A or B group. (Hiding random allocation and staying out of the intervention group)

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

11 km of Nazlou Road, Urmia University of Medical Sciences

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2016-10-16, 1395/07/25

Ethics committee reference number

IR.UMSU.REC.1395.248

Health conditions studied

1

Description of health condition studied

Colorectal cancer

ICD-10 code

C18.9

ICD-10 code description

Malignant neoplasm of colon, unspecified

Primary outcomes

1

Description

the severity of depression, anxiety and stress

Timepoint

First and 2 months after the intervention

Method of measurement

Roy review And recognition form and anxiety scale, depression, stress DASS-21

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Roy follow-up care model

Category

Diagnosis

2

Description

Control group: Chemotherapy and routine nursing and

medical care that are applied on a daily basis, and does not receive a training program based on the Roy adaptation pattern.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam khomeini hospital

Full name of responsible person

Nader aghakhani

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Ershad street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

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Resalat Boulevard - Emergency Coy

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Nader aghakhani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The original outcome information can be shared.

When the data will become available and for how long
2019

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
By citation

From where data/document is obtainable
Corresponding author

What processes are involved for a request to access data/document
Submit the documentation request to Corresponding author and review the application and submit the documentation

Comments