

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 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

##### Email address

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

**Street address**

Ershad street

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714783734

**Phone**

+98 44 3223 4897

**Email**

hazrati.a1990@yahoo.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Nader aghakhani

**Street address**

Resalat Boulevard - Emergency Coy

**City**

urmia

**Province**

West Azarbaijan

**Postal code**

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**Phone**

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**Email**

hazrati.a1990@yahoo.com

**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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**Person responsible for scientific inquiries**

**Contact**

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**Position**

Academic staff

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Nader aghakhani

**Position**

Academic staff

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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**Email**

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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**