

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparing the effect of adaptation nurturance using the Adaptive Potential Assessment Model (APAM) and routine education praogram on the self-efficacy and quality of life of patients with colorectal cancer undergoing chemotherapy

Protocol summary

Study aim

Determining The effect of adaptation nurturance by using the Adaptive Potential Assessment Model (APAM) on the self-efficacy and quality of life of patients with colorectal cancer undergoing chemotherapy

Design

a randomized clinical trial with a control group in parallel groups in the third phase without blinding, which will be conducted in the chemotherapeutic department. Seventy patients will be randomly allocated into two groups using Excel software.

Settings and conduct

Colorectal cancer patients hospitalized in the chemotherapy departments of Omid and Ghaem hospitals in Mashhad in two intervention and control groups without blinding in two phases in person and by telephone during two phases of chemotherapy

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 30 to 80 years old; Colorectal cancer diagnosis based on biopsy results and confirmation by a specialist; have a caregiver at home; not diagnosed with mental disorder; familiarity with the Persian language; Having the ability to speak; Equipped with a smartphone. Exclution criteria: Stage IV of cancer; Evidence of metastasis in the description of the patient's operation

Intervention groups

The intervention group will have at least 3 sessions of 30 to 45 minutes in person during hospitalization and then telephone counseling in a week until two months after the start of the intervention. The intervention includes fostering adaptability based on the patient's potential adaptability review model, which will be done based on Erikson's role modeling and modeling theory. The control group receives hospital training program.

Main outcome variables

self efficacy, quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150607022592N3**

Registration date: **2023-11-06, 1402/08/15**

Registration timing: **prospective**

Last update: **2023-11-06, 1402/08/15**

Update count: **0**

Registration date

2023-11-06, 1402/08/15

Registrant information

Name

nahid aghebati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-08, 1402/08/17

Expected recruitment end date

2024-06-06, 1403/03/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of adaptation nurturance using the Adaptive Potential Assessment Model (APAM) and routine education praogram on the self-efficacy and quality of life of patients with colorectal cancer undergoing chemotherapy

Public title

The effect of adaptation nurturance on the self-efficacy and quality of life of patients with colorectal cancer undergoing chemotherapy

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Being at the age of 30-80 years old Having Colorectal cancer with an oncologist special diagnosis Having a caregiver at home Being Persian Having the ability to speak Having a personal smart phone

Exclusion criteria:

Reducing level of consciousness and being refereed to ICU Evidence of metastasis in the description of the patient's operation Having a diagnosed psychological disease

AgeFrom **30 years** old to **80 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

At first, using statistical software, 18 permutation blocks of size 4 will be recovered. Then the units of each block are placed separately in sealed envelopes. Before starting the sampling, the researcher asks one of the ward nurses to open the first envelope and open the characters inside the envelope for the researcher, according to the patients who met the criteria for entering the study and consent to participate in the study with the help of the consent form. They have consciously announced that they will be placed in the intervention and control groups in parallel. This process will continue until the completion of the samples in two groups based on the sample size of 70 people (35 people in each group).

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**

Research Ethics Committees of School of Nursing & Midwifery; Mashhad University of Medical Sciences

Street address

Nursing and Midwifery School; Shahid Dr Kharazmi Educational institute ;Pardis of Mashhad university of Medical Sciences; The East door of Ferdowsi University; Azadi Square, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2023-07-11, 1402/04/20

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.081

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

Colorectal Cancer

ICD-10 code

C18-C21

ICD-10 code description

Malignant neoplasms of digestive organs: Malignant neoplasm of colon, Malignant neoplasm of rectosigmoid junction, Malignant neoplasm of rectum, Malignant neoplasm of anus and anal canal

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

Self-efficacy score

Timepoint

Before the intervention - the first month and the second month after the start of the study

Method of measurement

Cancer Behavior Inventory-Brief Version (CBI-B)

2**Description**

Quality of life score

Timepoint

Before the intervention; 1 month and 2 months later
Method of measurement
Quality of life questionnaire-cancer 30 (EORTC QLQ-C30)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention begins in the second phase of chemotherapy after obtaining informed consent. First, questionnaires to check demographic information, self-efficacy and quality of life are completed by the patient. adaptation Nurturance as an intervention of the present study is implemented in two stages of modeling and role modeling. Nurturance includes educational, supportive and caring interventions. In the modeling stage, the researcher tries to gain the patient's trust and use the process of active listening to determine the patient's adaptation status by using a questionnaire to determine the degree of adaptation based on the nursing theory of modeling and role modeling and determine the existing stressors. Then, a pattern of the patient's adaptation status is drawn, including three phases: arousal, equilibrium, and impoverishment. At this stage, the researcher can determine the patient's condition based on the identification of various internal and external stressors (related stressors of colorectal cancer patients according to existing articles It often includes the disorder of imbalanced nutrition less than body requirements, decreased fluid volume, not knowing how to take care of the colostomy bag, as well as nausea and vomiting and diarrhea caused by chemotherapy.) But based on the unique needs of each patient some other the stressors might be determined. Then, in the role modeling stage, the researcher tries to bring the patient's educational support closer to balance by using appropriate care interventions, if the patient is in the phase of equilibrium or impoverishment. The researcher tries to implement the process of modeling and role modeling for the patient during 3 to 5 face-to-face sessions of 30 to 45 minutes. At least two face-to-face sessions are held in each chemotherapy period. And between the chemotherapy courses, video communication is established with the patient twice using the virtual network, and the patient's condition is evaluated and the necessary recommendations are given to the patient. In the third and fourth stages of chemotherapy (one month and two months after the start of the intervention), the level of self-efficacy and the quality of life of the patient are measured.

Category

Rehabilitation

2

Description

Control group: In the control group, all the usual care and

training is done in hospitals, which includes the use of educational pamphlets and participation in health clinic training programs. along with participation in the telephone follow-ups that are done by the nurses of the health clinic of the hospitals. Educational measures and follow-ups by phone and virtual network are done in the intervention group with the coordination of the hospital's health education clinic.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Nioosaha Pahnavar Roudi

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2

Recruitment center

Name of recruitment center

Qaem Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Research and Technology Deputy; The Ghoreishi building; Next to Hoveizeh cinema; Daneshgah street

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Web page address

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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

Person responsible for general inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Aghebati

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Nursing and Midwifery School; Shahid Dr Kharazmi Educational institute ;Pardis of Mashhad university of Medical Sciences; The East door of Ferdowsi University; Azadi Square, Mashhad

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Associate Professor

Latest degree

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available