Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of family and patient-centered empowerment program on quality of life and quality of social communication in patients with colorectal cancer: A clinical trial study

Protocol summary

Study aim
To Investigate the effect of family and patient-centered empowerment program on quality of life and quality of social communication in patients with colorectal cancer

Design
Clinical trial with control group, randomized, with parallel groups, design of 60 patients

Settings and conduct
The samples were selected from among all colorectal cancer patients referred to the chemotherapy department of Peymaniyeh Hospital in Jahrom city were randomly divided into two intervention and control groups. The case group will receive the empowerment program in addition to routine care in 8 training sessions, twice a week in the form of lectures, questions and answers, film screenings, an educational pamphlet. Primary caregivers will be present with patients in all training sessions.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: - Patient and primary caregiver's willingness and consent to participate in the study. - Patient and primary caregiver's ability to read and write. - Patient and primary caregiver must be over 18 years of age. - The diagnosis of colorectal cancer must be confirmed by an oncologist Exclusion Criteria - Suffering from obvious psychological disorders (such as depression, psychosis, mania) and mental disorders of the patient and the main caregiver

Intervention groups
Intervention group This stage will be carried out in four steps through group discussion sessions for patients and their families. First Step (Perceived Threat), Second Step (Self-Efficacy Promotion), Third Step (Self-Esteem Enhancement) and Fourth Step (Final Evaluation). Control Group The control group will receive routine care.

Main outcome variables
quality of life; quality of social communication

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230730058966N2**
Registration date: **2024-11-18, 1403/08/28**
Registration timing: **prospective**

Last update: **2024-11-18, 1403/08/28**
Update count: **0**

Registration date
2024-11-18, 1403/08/28

Registrant information

Name
mahdi karimyar jahromi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-21, 1403/09/01

Expected recruitment end date
2025-03-05, 1403/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of family and patient-centered empowerment program on quality of life and quality of social communication in patients with colorectal cancer: A clinical trial study

Public title
family and patient-centered empowerment in colorectal cancer

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patient and primary caregiver's willingness and consent to participate in the study Patient and primary caregiver's ability to read and write Patient and primary caregiver must be over 18 years of age The patient and primary caregiver must not have psychiatric disorders (such as depression, psychosis, mania) or mental disorders The primary caregiver should live with the patient The primary caregiver must be an active member of the patient's care The diagnosis of colorectal cancer must be confirmed by an oncologist

Exclusion criteria:
Absence of the primary caregiver and the patient for more than 2 sessions Death or migration of the patient Lack of cooperation or willingness of the primary caregiver to continue participating in the study Incomplete filling of questionnaires by the patient

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
First, a list of selected samples is prepared and numbered in order. Then, with the help of "Random Number Generator" software, each of the even numbers obtained in each selection will be assigned to the control group and the odd numbers will be assigned to the case 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 Jahrom University of Medical Sciences

Street address
Deputy of Research and Technology, Jahrom University of Medical Sciences, Motahari st.

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Fars

Postal code
7414846199

Approval date
2024-10-16, 1403/07/25

Ethics committee reference number
IR.JUMS.REC.1403.069

Health conditions studied

1

Description of health condition studied
colorectal cancer patients

ICD-10 code
C19

ICD-10 code description
Malignant neoplasm of rectosigmoid junction

Primary outcomes

1

Description
quality of life

Timepoint
before intervention and immediately and 1 month after intervention

Method of measurement
The Quality of Life Questionnaire for Colorectal Cancer Patients (QLQ-CRC)

2

Description
quality of social communication

Timepoint
before intervention and immediately and 1 month after intervention

Method of measurement
The Social Relationship Quality Scale (SRQS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This stage will be carried out in four steps through group discussion sessions for patients and their families. In this stage, based on the results obtained from the questionnaires in the previous session, individuals will be categorized into groups of 5 to 7 people with common needs, and guidance and training related to emphasizing the importance of improving social relationships and methods to improve the quality of life of patients will be provided in four steps over 8 sessions.First Step (Perceived Threat): Includes perceived severity and sensitivity. This step will be conducted in 2 sessions using educational pamphlets and films, and the educational content will include: familiarity with the anatomy and physiology of the intestine and digestive system, acquaintance with colorectal cancer and its treatment methods, symptom management (prevention and reduction of nausea and vomiting, skin and hair damage, fatigue, defecation problems), and mentioning specific examples of their own symptoms. In these sessions, the researcher will have a supportive, guiding, and participatory educational role. The duration of each session will be 40 to 60 minutes, depending on the patients' preference. At the end of each session, there will be a summary and a question-and-answer session, and an educational card containing the session materials will be provided to the patient and the primary caregiver.Second Step (Self-Efficacy Promotion): Four 1-hour sessions will be held using the problem-solving method or group problem-solving. Patients will start the discussion by mentioning their own problems, and their problems will be identified, defined, and prioritized by themselves, then skillful solutions will be taught through scientific demonstration and group discussion. Patients and their families will participate in suggesting and choosing solutions. In these sessions, issues such as self-care in colorectal cancer, family involvement, management of negative emotions and psychological issues (reducing anxiety and depression, stress, and anger), mindfulness, improving sleep patterns, defecation patterns, ways to promote spiritual activity, improving social interactions, increasing positive activities, scheduling a written reminder of medication time, observing health points, and managing fatigue will also be discussed, and muscle relaxation techniques and sports exercises will be demonstrated.Based on the group discussion, the researcher will realize:1- To what extent the educational content has been successfully conveyed 2- Points that have not been conveyed to the patients and active family members will be discussed, and 3- Questions from the active family member and the patient will be answered. In this stage, patients and their families will mentally and practically believe that they can prevent and control the consequences of chemotherapy and its side effects by self-control and adopting preventive behaviors. Patients and active family members will study the pamphlets and ask questions on the subject to the researcher.Third Step (Self-Esteem Enhancement): This step will be conducted using the participatory education method in 1 session. The patient will learn the topics and skills with their active family member. The active family members and the patient will be asked to discuss the topics they will be taught and what they will learn from the educational pamphlets and films under the supervision of the researcher. Then, patients will be asked to practice and repeat the behaviors and skills they have learned to become self-sufficient to the extent that they can perform them without the presence of the researcher. The feeling of learning, the feeling of being able to do so, and receiving encouragement from themselves and the researcher will increase the patient's self-sufficiency and, consequently, their self-esteem. Also, during the self-efficacy and self-esteem intervention, the researcher will evaluate the level of adopting preventive behaviors in each session by asking questions about the correct implementation or elimination of the wrong behavior in relation to the previous session. In these sessions, topics will be expressed by the active family member and the patient, and the researcher will play a facilitating role.Fourth Step (Final Evaluation): The final evaluation will be conducted in 1 session immediately after and one month after the end of the empowerment model. The perceived threat will be evaluated by asking questions about the content of the previous sessions. Self-efficacy will be evaluated by performing the taught skills (such as muscle relaxation techniques, sports movements, etc.). Self-esteem will be evaluated by asking and assessing the level of cooperation and interest of the patient and family in educational participation.

Category

Rehabilitation

2

Description

Control group: The control group will receive routine care.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Peymaneh Hospital of Jahrom University of Medical Sciences

Full name of responsible person

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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
Jahrom 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

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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
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
all collected deidentified IPD
When the data will become available and for how long
starting immediately after publication
To whom data/document is available
all people
Under which criteria data/document could be used
There is no special condition. Any request will be answered by email. There will be no specific restrictions on the use of data or documents.
From where data/document is obtainable
Request by email to: mahdikarimyar310@gmail.com
What processes are involved for a request to access data/document
If the request is received by email, it will be answered as soon as possible.
Comments