

Development a Palliative Care Program for Colorectal Cancer Patients: A Mixed Methods Protocol study

Masoumeh Masoumy, Masoud Bahrami, Alireza sadeghi, Rohallah Mosavizadeh

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Masoumeh Masoumy¹; Masoud Bahrami¹ PhD; Alireza sadeghi²; Rohallah Mosavizadeh³

¹Faculty Of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran Isfahan IR

²Cancer Prevention Research Center, Department of Hematology-Oncology, Isfahan University of Medical Sciences, Isfahan, Iran Isfahan IR

³ALA cancer prevention and control center, Department of Islamic Education, Isfahan University of Medical Sciences, Isfahan, Iran Isfahan IR

Corresponding Author:

Masoumeh Masoumy

Abstract

Background: Introduction: Colorectal cancer (CRC) is the third most common cancer in Iranian men and the second in Iranian women and it is a serious health problem in the Iran health system.

Objective: The purpose is to develop a holistic palliative care program in order to improve the health and quality of life of colorectal cancer patients.

Methods: This is an exploratory mixed methods study which will be conducted using a sequential qualitative-quantitative design (QUAL + quan) consists of four sequential steps using the approach proposed by Ewles & Sminett to develop the program. In the first step, a qualitative study (semi-structured interview), the researcher discovers the needs of colorectal cancer patients from the perspective of patients, family members and care providers. In the second step, the literature review will be performed with the aim of confirming and completing the discovering new needs. In the third step, a initial draft of the palliative care program will be developed based on data extracted from qualitative study and literature review, experts' panel opinions. In the fourth step, according to the opinions of the panel of experts, the part of the developed program will be implemented as quasi-experimental intervention and the effect of intervention on quality of life will be evaluated.

Results: This study can will provide a better understanding of the demands and problems of colorectal cancer patients and their families through providing a holistic care and improve their quality of life in the socio-cultural context of Iran. This program can be useful in providing care, education, policy making, future research and colorectal cancer patients' health promotion.

Conclusions: This study can will provide a better understanding of the demands and problems of colorectal cancer patients and their families through providing a holistic care and improve their quality of life in the socio-cultural context of Iran. This program can be useful in providing care, education, policy making, future research and colorectal cancer patients' health promotion.

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Original Manuscript

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Masoud Bahrami¹, Masoumeh Masoumy^{2*}, Alireza Sadeghi³, Rohallah Mosavizadeh⁴

1. Ph.D., Professor, Cancer Prevention Research Center , Faculty Of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran

2. Ph.D. student in nursing, student Research Committee, Faculty Of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran

3. Assistant Professor, Cancer Prevention Research Center, Department of Hematology-Oncology, Isfahan University of Medical Sciences, Isfahan, Iran

4. Assistant Professor, ALA cancer prevention and control center, Department of Islamic Education, Isfahan University of Medical Sciences, Isfahan, Iran

* Corresponding author: Ph.D. student in nursing, Student Research Committee, Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran. Email: ,masoumy @nm.mui.ac.ir

Phone number: 09171465542

Abstract

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Discussion: This study can will provide a better understanding of the demands and problems of colorectal cancer patients and their families through providing a holistic care and improve their quality of life in the socio-cultural context of Iran. This program can be useful in providing care, education, policy making, future research and colorectal cancer patients' health promotion.

Keywords: Palliative Care, Colorectal Cancer, Mixed Methods, Protocol Study, Nursing

1. Background

According to the Globocan site in 2018, 1.8 million new cases of CRC¹ and 700,000 deaths caused by it have been reported in the world[1]. CRC is one of the most prevalent cancers of the gastrointestinal tract in Iran, which is the third most common in Iranian men and the second in Iranian women[2]. The prevalence of CRC in Isfahan province has been about 52.6 per 100,000 people, showing a significant increase in the prevalence of it from 2011 to 2015. Based on these statistics, CRC is an serious health problem in the country, especially in Isfahan province[3].

Knowing about one's cancer is a shocking and worrying experience which can lead to various physical, psychological, social, financial and spiritual problems. These patients experience physical treatment-caused complications and psychological problems including anxiety, fear, depression and mental imbalance. Moreover, multiple hospitalizations for treatment can prevent the continuation of normal life and return to work, and lead to the feeling of isolation and loss of independence in these patients [4-6]. High levels of psychological distress are associated with decreased quality of life, non-adherence to treatment, and poorer prognosis [7]

¹ .Colorectal Cancer

Additionally, the population CRC survivors is increasing day by day[8] This means that improving the survival of patients imposes new challenges such as caring for the long-term complications of the treatment and maintaining the quality of life of patients upon the care provider[9]. Therefore, unlike the past, today the quality of life is assessed as one of the important outcomes and indicators determining the effect of treatment in patients. Improving the quality of life of cancer patients has been one of the main goals of care and treatment of cancer patients[10].

Therefore, the troublesome symptoms and complications of cancer and its treatments, on the other, and the huge treatment costs imposed on the patients and their families, make these patients in need of quality-enhancing care. Accordingly, these patients are among the incurable groups who need comprehensive care in the form of "supportive and palliative care"[11]. In fact, palliative care includes all active and complete measures which are taken to reduce pain and improve the quality of life of patients[12]. According to studies, patients at different stages of CRC need palliative care to improve their symptoms, as 30% of CRC patients at the time of diagnosis are in the advanced stages of the disease and 40% to 65% of all patients with CRC are in the metastatic stage[13]. Studies have confirmed the benefits of integrating palliative care into oncology. What the results of these studies show are an improvement in patients' quality of life, less depressive symptoms, less aggressive end-of-life care, and more patient and caregiver satisfaction with the received care[14] In other words, providing palliative care in the form of specialized services may lead to better control of the symptoms, pain management, reduced patient and family anxiety and provision of high-quality care, the reduction of unwanted hospitalizations, improved quality of life and reduced economic burden of cancer on the health system[15, 16].

Depending on which part of the intestine is involved in cancer, ostomy bags will be placed for patients and patients with ostomy will suffer from various physical, psychological, social, financial and sexual problems in the long-term. Because this ostomy bag and the annoying smell and sound of this bag are always with them, as a result, the quality of life of patients and their families will decrease despite disease control. Therefore, designing a specific palliative care program for these patients is necessary due to having different problems caused by digestive or ostomy problems. The high prevalence of CRC in Iran is an important health problem for the country, and patients with this disease need palliative care services at all stages of the disease along with the main treatments. Therefore, it is necessary to identify the needs of CRC patients in Iran based on the country's characteristics and underlying conditions and, then, design and implement a program tailored to the needs of these patients. Therefore, in order to provide integrated and comprehensive palliative care to these patients, a mixed methods study (qualitative and quantitative) will be used.

Objective

The aim of this study is designing, implementing and evaluating palliative care program for CRC patients.

Materials and Method

This is an exploratory sequential study(QUAL →quan) will be done in 4 steps. Ewles & Sminett (2010) model will be used to develop the program[17]. Studies that explore the CRC patients needs have not been performed in Iran, so in this study, the qualitative stage has more priority

Phase1 Qualitative Study

A qualitative study, using in-depth semi-structured interviews and field note and memoing will be conducted to discover and identify the needs of colorectal cancer patients and challenges and strategies to meet needs from the viewpoint of the patients, their families and health care providers.

Study participants

The participants in this phase will include CRC patients, their family members and health service providers including oncologists, oncology nurse, psychologist, spiritual caregiver, social worker, and nutritionist. The purposive sampling method will be used with maximum diversity in sex, age, education level, occupation.

Inclusion Criteria

colorectal cancer patients

- desire to participate in the study
- undergoing chemotherapy and radiotherapy or having received them
- being in the stages 2 and 3 of the diseases and not being in the metastasis stage and end stage

Family caregivers

- desire to participate in the study
- who have experienced continuous care of a patient with colorectal cancer at home

Health Care Providers

- have worked for at least 6 months in adult cancer or palliative care wards
- desire to participate in the study

Exclusion criteria

- Reluctance to continue cooperation
- withdrawal from the study at any stage of the research

Procedure

The study setting includes cancer treatment centers and ALA Center Control and Prevention Cancer (MACSA) in Isfahan. The data will be collected through in-depth semi-structured interviews using an interview guide. For ethical considerations, the purpose of the study will be explained to the participants before the interview and informed written consent will be obtained from the participants for recording the interviews, and the place and duration of the interviews will be determined according to the preferences of the participants. Initial guiding questions will be extracted from the relevant literature and provided in 3 parts by considering the related participants groups.

The first part will be comprised of the questions related to CRC patients to identify needs, problems and concerns and requires health services. The data obtained from this section will provide useful information about needs and challenges to meet the needs of these patients.

The second section is the questions related to family caregiver. The purpose of these questions is to identify the impact of the disease on various aspects of your patient's life, your patient's needs after diagnosis CRC. The third part of the questions will be related to HCP. The purpose of questions in this part is to identify cares and services required by these patients when providing care to these patients. The interviews which will be continued until data saturation. Data analysis will be performed simultaneously with data collection using the qualitative content analysis based on Graneheim and Lundman approach[18]. The interviews will be transcribing verbatim and the researcher will read the text of the interviews several times and its meaning units will be identified. Then, the main idea in important sentences and items will be tagged as code. After the same initial codes will be put together, the data will be reduced and finally categories of the codes will appear. The MAXQDA 10 software will be used for the management of the data. In order to trustworthiness of the qualitative data of four criteria including credibility, transferability, dependability and confirmability are used[19]. The following measures include selecting participants with maximum variation, allocating sufficient time to data collection and using various data collection methods such as interviews and field observations and check the accuracy of the researcher's perception through review a sample of the codes by an outsider observer and participants will be increase credibility. By comprehensive describing all the steps of the research so that other researchers can do the same steps will be increase transferability. In order to increase confirmability, the study steps will be accurately recorded so that a thorough audit of the work is possible.

Phase2 literature review

In this phase, the researcher will be conducted searching multiple electronic databases including

Scopus, MEDLINE, Proquest, Web of Science(SID), Embase with mesh-matching keywords like the “Palliative Care”, “Colorectal Cancer”, "need", "unmet needs" will be searched for the related articles from 2010 to 2021. Persian databases in SID, Magiran and Iranmedex will be searched with the Persian keywords for the related articles from 2010 to 2021. The purpose of this phase is to confirm the needs discovered in the qualitative phase or to discover the new needs and categories and to discover the strategies to meet the needs of CRC patients in related texts.

Inclusion Criteria

- The full text of the original articles (quantitative, qualitative and mixed methods) , review articles, book reviews
- Articles published between 2011 and 2021
- Articles are published in English or Persian languages

Exclusion criteria

- Articles related to advanced CRC patients/survivors 'needs
- Abstracts, short communications, letters to the editors
- articles without having access to their full text

Phase3 Development of palliative care program

In this step, Ewles & Sminett model (2010) will be used to develop the program, which the steps of this model include identifying needs and prioritize needs, identifying general and specific goals, selecting the best strategies to achieve specific goals, identifying resources, evaluation methods of program, and determining intervention activities. In order to prioritize needs and to identify goals and selecting the best strategies and to identify evaluation methods and type intervention will be used Experts panels.

Study participants

The member of experts will include oncology nurse, Oncologist, Physicians, Psychologists, Social workers, Nutritionists, Spiritual caregiver, faculty members and other experts who provide care to patients with CRC.

Inclusion criteria

- Having experience and expertise in providing care to patients with CRC
- Having experience in palliative care, CRC and cancer studies
- Desiring to participate in the panel sessions.

Exclusion criteria

- Reluctance to participate in panel meetings
- Failure to attend in at least two sessions.

Procedure

Expert panel members will be selected using purposive and snowball sampling methods. The number of participants will be at least ten[20]. Before the meeting, a list of extracted palliative care needs and the goals of the panel will be provided to specialists along with the written invitation. At the beginning of the session, the researcher will provide a summary of the research methodology as well as the data obtained from the qualitative study and literature review and objectives of the panel session. Then of Experts group will be asked to score needs and strategies based on criteria of "importance", "cost", and "applicability" in 5-point Likert (1 lowest and 5 highest)[21]. Then, experts groups will discuss the needs and priority strategies as well as the type of intervention to meet the needs of these patients and the evaluation methods of the intervention and will present their suggestions. The researcher will record and take notes of the expressed titles, in order used to design the Program. Once the priority needs and strategies have been identified, the initial draft of the palliative care program for CRC patients will be developed. Then the initial plan prepared to confirm the content will be sent via email to the same specialists participating in the panel meeting,

and after receiving the experts' suggestions, the necessary corrections will be made and the developed palliative care plan will be finalized.

Phase 4 Program implementation and evaluation

In order to determine the effectiveness the part of program focuses on meeting the needs and improvement quality of life of CRC patients, a pretest–posttest quasi-experimental a with nonequivalent group design will be implemented.

Study participants

It will be included all colorectal cancer patients. Patients will be selected using convenient sampling[22].

Inclusion criteria:

- patients has been diagnosed in the stages 2 and 3 disease
- patients undergoing chemotherapy and radiotherapy or those who have received these treatments
- have not existence of metastasis

Exclusion criteria

- Reluctance to collaborate at any stage of research
- Absence in 2 sessions of intervention sessions

Procedure

After receiving the code of ethics from the ethics committee of Isfahan University of Medical Sciences (IUMS), the researcher will go to the research environment that will be included hospitals centers providing care to CRC patients as well as palliative care centers in Isfahan. In this study, people who meet the inclusion criteria will be selected by convenient sampling method, so that the researcher written informed consent will be taken from the samples and the samples will be randomly assigned to the control or intervention groups. The number of samples will be calculated based on the formula of the sample size.

$$n = \frac{2(z_1 + z_2)(s)^2}{(d)^2}$$

After determining the type of intervention according to the experts group comments, in the intervention group, the intervention will be implemented, and the control group will not receive any intervention. After completing the intervention sessions for the intervention group, a similar package will be provided for the samples in the control group. Impact of intervention will be evaluated using the standard questionnaires will be completed by both groups, before and after the implementation of the intervention.

The tools used to collect information including demographic questionnaire and QLQ-CR29² questionnaire and also in accordance with the type of intervention performed other valid and reliable questionnaires will be used to evaluate the effectiveness of the intervention.

QLQ-CR29 questionnaire is the quality of life questionnaire for colorectal cancer. This questionnaire belongs to the European Organization for Research and Treatment of Cancer [23]. It is a self-administered tool consisting of 29 questions designed to assess the quality of life of CRC patients. The answers in the form of a 4-point Likert scale range from 1 to 4, and the final score of the questionnaire for the performance indicators ranges from zero (worst health condition) to 100 (best health condition) and for the symptom indicators from zero (no symptoms) to 100 (maximum symptom). The questions of the questionnaire are related to the patient's condition in the past week, except for sexual function which is related to the last four weeks[24]. The validity and reliability of QLQ-CR29 have been measured in Khazaeli study (2013) and the total Cronbach's alpha of the

² .Quality Of Life Questionnaire Colorectal Cancer 29

questionnaire has been equal to 0.89[25].

Data Analysis Method

The data will be analyzed using descriptive and inferential statistical methods in SPSS20 software.

Integration of data

In this research, integration of data will be conducted by quantitative and qualitative results will be expressed together in the discussion.

Discussion

Iranian society is transitioning from experiencing various changes in social aspects, including changes in the lifestyle of people, changes in the population pyramid, such as population aging, the reduction of the age of diseases, and new methods of treatments for chronic diseases which affect the survival and health status of people. To reach new horizons and deal with these challenges, the most important of which is CRC, the service delivery system must show an appropriately and timely response to these changes.

Providing palliative care is considered as one of the main necessities of the health system, especially in cases where CRC and the rate of the related deaths are high and, thus, there is a need for specialized and supportive care, pain management and symptom control. In the area of providing palliative care, the philosophy and mission of this care is the same in all parts of the world. Assessing the needs of the patients, palliative care is based on providing comprehensive and holistic care for patients. Thus, this study is developing the first palliative care program for CRC patients based on needs, experiences patients and the socio-cultural condition of Iran[26].

The program developed in this study can be given to members of the health team as a guide to improve the quality of life of patients with CRC. Developed based on a holistic approach, this program will help members of the health team to provide care in the form of an inter-professional team. Providing care by using this program helps to pay more attention to the necessity of a holistic view to patients and their family through considering their various physical, psychological, spiritual and material dimensions in their care, provide the patients with better services and satisfaction, reduce psychological distress, and improve the quality of life of CRC patients. Moreover, based on the developed program, strategies and procedures for meeting the different needs of CRC patients will be extracted by reviewing the related literature and interviewing patients, their families and members of the health team. Using these strategies together with the cooperation of health team members, will improve the quality of care and, consequently, the quality of life of these patients. Given the lack of a holistic palliative care program for CRC patients as well as the focus of some studies on the physical aspects of palliative care in these patients, this study is an attempt to find palliative care needs in CRC patients and develop a care program for them. As such, this study will be a step towards the promotion of a new palliative care in Iran.

Conclusion

Designing a palliative care program for patients with CRC, in addition to controlling physical symptoms, other aspects of quality of life such as psychological, social, spiritual dimension will be considered and will improve the quality of life and health of patients in all dimensions.

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Footnotes

Authors' contributions: MM, MB, AS, and RM were involved in study conception, design and drafting of the manuscript. MM wrote the first draft of this study protocol. MB, AS, and RM reviewed the first draft of the protocol and manuscript. MB were responsible for coordinating the study. MM will be responsible for interview with participants, description and data analysis. MB, AS and RM will review and will involve in data analysis and qualitative phase. MM will be responsible for delivering and intervention. MB Will provide the quantitative design. All authors read and approved the final manuscript.

Conflict of Interests: The authors declare that they have no conflicting interests.

Ethics approval: Ethical approval this study has been attained by the Ethics Committee of the Isfahan University of Medical Sciences, Isfahan, Iran(codenumber:IR.MUI.Research.Rec.1399.126).

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