

Self-Management Program in Adults with Colorectal Cancer: A Pilot Study*

* Extracted from the Ph.D. thesis *Nursing intervention for self-management in adults with colorectal cancer undergoing surgical treatment*, submitted to the Ph.D. Nursing program of the Universidad Nacional de Colombia in 2020.

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Theme: Evidence-based practice.

Contribution to the discipline: The study contributes to the design of a nursing intervention that takes up approaches from the theory of individual and family self-management through the integration of aspects not only of instruction, education, and follow-up but also the strengthening of the role of human talent as “facilitator” and guide of processes that the patient must consolidate.

Abstract

Objective: To design and validate a nursing intervention and its effect on improving self-management behaviors in patients with colorectal cancer following surgery within eight weeks after discharge. **Method:** Pilot study using Sidane and Braden's intervention design proposal, which included determining the guiding theoretical model, characterization of the intervention, validation with eight experts through content validity, and a pilot test with ten patients during the second semester of 2020. **Results:** The intervention obtained, called the Program for Self-Management Training in Colorectal Cancer (PEACCR, by its acronym in Spanish), is based on the theory of individual and family self-management in the dimensions proposed by Ryan and Sawin. The validity with experts indicates that it meets the criteria of clarity, precision, comprehension, relevance, and pertinence. The pilot reports an increase in self-management behaviors and the dimensions of knowledge, coping, and health personnel-patient alliance in months 1 and 2, with statistical significance. **Conclusions:** The designed and validated intervention increases the self-management behaviors of patients with colorectal cancer. The proposed scheme is highly acceptable to participants.

Keywords (Source: DeCS)

Self-management; colonic neoplasms; patient discharge; treatment outcome; evaluation of the efficacy-effectiveness of interventions; nursing.

4 Programa de automanejo en adultos con cáncer colorrectal: estudio piloto*

* Extraído de la tesis de doctorado: *Intervención de enfermería para el automanejo en adultos con cáncer colorrectal en tratamiento quirúrgico*, presentada al programa de Doctorado en Enfermería de la Universidad Nacional de Colombia, en el año 2020.

Resumen

Objetivo: diseñar y validar una intervención de enfermería y su efecto para mejorar los comportamientos de automanejo en pacientes con cáncer colorrectal, después de una intervención quirúrgica dentro de las ocho semanas posteriores al alta. **Método:** estudio piloto que acoge la propuesta de diseño de intervenciones de Sidane y Braden, lo que incluyó determinar el modelo teórico orientador, la caracterización de la intervención, la validación con ocho expertos a través de la validez de contenido, y una prueba piloto con diez pacientes, durante el segundo semestre del año 2020. **Resultados:** la intervención obtenida, denominada Programa para el Entrenamiento en Automanejo en Cáncer Colorrectal (PEACCR), se basa en la teoría de automanejo individual y familiar en las dimensiones planteadas por Ryan y Sawin. La validez con expertos indica que cumple con los criterios de claridad, precisión, comprensión, relevancia y pertinencia. El piloto reporta un aumento en los comportamientos de automanejo y en las dimensiones de conocimiento, afrontamiento y alianza personal de salud-paciente en el mes 1 y en el mes 2, con significancia estadística. **Conclusiones:** la intervención diseñada y validada aumenta los comportamientos de automanejo de pacientes con cáncer colorrectal. El esquema propuesto es de alta aceptabilidad para los participantes.

Palabras clave (Fuente DeCS)

Automanejo; neoplasias del colon; alta del paciente; resultado del tratamiento; evaluación de eficacia-efectividad de intervenciones; enfermería.

Programa de autogestão em adultos com câncer colorretal: estudo-piloto*

*Extraído da tese do doutorado “Intervenção de enfermagem para a autogestão em adultos com câncer colorretal em tratamento cirúrgico”, defendida no âmbito do programa de doutorado em Enfermagem da Universidad Nacional de Colombia, em 2020.

Resumo

Objetivo: desenhar e validar uma intervenção de enfermagem e seu efeito para melhorar os comportamentos de autogestão em pacientes com câncer colorretal, depois de uma intervenção cirúrgica dentro das oito semanas posteriores à alta. **Materiais e método:** estudo-piloto que utiliza a proposta de desenho de intervenções de Sidane e Braden, o que inclui determinar o modelo teórico orientador, a caracterização da intervenção, a validação com oito especialistas por meio da validade de conteúdo e um teste-piloto com dez pacientes, durante o segundo semestre de 2020. **Resultados:** a intervenção obtida, denominada “Programa para o Treinamento em Autogestão em Câncer Colorretal”, está baseada na teoria de autogestão individual e familiar nas dimensões propostas por Ryan e Sawin. A validade com especialistas indica que cumpre com os critérios de clareza, precisão, compreensão, relevância e pertinência. O piloto relata um aumento nos comportamentos de autogestão e nas dimensões de conhecimento, enfrentamento e parceria pessoal de saúde-paciente no mês 1 e no mês 2, com significância estatística. **Conclusões:** a intervenção desenhada e validada aumenta os comportamentos de autogestão de pacientes com câncer colorretal. O esquema proposto é de alta aceitabilidade para os participantes.

Palavras-chave (Fonte: DeCS)

Autogestão; neoplasias do colo; alta do paciente; resultado do tratamento; avaliação de eficácia-efetividade de intervenções; enfermagem.

Introduction

Colorectal cancer (CRC) is a neoplastic disease of public health interest of a preventable type; however, in Colombia for the year 2020, it is estimated that 10,783 people suffered from this disease, corresponding to 10.4 % of CRC cases in South America. Compared to other countries in the region, Colombia ranks third in the prevalence of CRC, after Brazil and Argentina; by 2020, 54,987 people died of this cause in Colombia. In addition, the Carvalho study provides evidence that cancer is related to lifestyle, dietary changes, and variations in CRC risk factor prevalence by sex. This epidemiological profile shows how, in both developed and developing countries, this disease is among the main causes of morbidity and mortality, causing economic consequences in the health system and deterioration in the quality of life of people in terms of physical, psychological, emotional, social and spiritual well-being (1).

The treatment of CRC includes surgery as the therapeutic option of choice in most cases. These treatments generate side effects, which involve modification of lifestyles, limitation, mutilation, and social and occupational readaptation (2).

The experience of people with CRC is a difficult experience that affects self-image since it involves learning to manage ostomies, adapting to the diet, facing a high emotional burden and uncertainty about the prognosis, as well as readapting to daily life without support and follow-up of the health team (3).

The current regulatory framework and scientific associations report the need to consolidate follow-up interventions for cancer patients (4) that include all phases of the disease and impact quality of life, are cost-effective, and encourage self-management with follow-up after surgery.

However, self-management is a strategy and one of the four goals of the strategic framework for improving the health status of individuals with multiple chronic diseases (5), which proposes to go beyond information to actively teach people to detect and solve the problems associated with the disease. Self-management programs should facilitate decision-making that favors well-being and involve dynamic, interactive processes of time, repetition, and reflection; they are accompanied by follow-up with the use of information and communication technologies, as effective strategies to manage the most frequent symptoms, such as pain (6), adherence to treatment, tolerance, physical activity and satisfaction with care.

For (7), self-management is defined as the assessment, planning, and implementation of appropriate care that allows the patient to cope with the disease until death through self-management and treatment of the disease and its side effects. A key aspect is that self-management support can provide more patient- and family-centered care when dealing with life-threatening illnesses.

For their part, (8) state that for self-management to be developed, the benefits of these programs must be identified in the populations involving health personnel and the health system to facilitate adherence and decision-making and to improve self-management skills to cope with a chronic disease.

Nursing has a fundamental role in implementing interventions aimed at promoting the self-management of patients with CRC to mitigate consequences, such as uncertainty, lack of knowledge about the disease, isolation, fear of recurrence, lack of decision-making, and loss of control over health. In this sense, it is required to go beyond managing skin lesions, post-surgical stoma, chemotherapy management, or unpleasant symptoms in people with CRC, as this is a determinant that allows taking a position in the context and becomes a challenge for health care.

However, several theoretical references addressing self-management, among which the mid-range nursing theory (Individual and Family Self-Management Theory [IFSMT]) of (9), define it as a complex and dynamic phenomenon consisting of three dimensions: context, process, and outcome.

Contextual factors are the dimensions that influence individual and family management of the self-management process and directly impact outcomes. They can be protective or risky and include: a) specific conditions: the complexity of the condition, treatment, and trajectory; b) the physical and social environment, including access to care, transition adjustment, providers, transportation, social and cultural capital; c) individual and family conditions: the family's state of development, perspectives, level of schooling, information process and capabilities (9).

The self-management *process*, in turn, includes a) knowledge and beliefs about self-efficacy, outcome expectancy, and goal congruence; b) self-regulation, skills, and abilities: goal setting, self-monitoring and reflective thinking, decision making, planning and action, self-evaluation, and emotional control; c) social facilitation, which involves influence, support, and collaboration between individuals, families, and health professionals.

Finally, the *result* can be proximal or distal. The proximal focuses on the self-management behavior of the specific condition and the cost of health services; the distal, on the other hand, on health status, quality of life or well-being, and the costs of both direct and indirect health services.

Accordingly, the study's objective was to design and validate an intervention based on the postulates of the nursing theory of individual and family self-management according to the context and the characteristics of access to the system of people with CRC (9).

Method

A pilot study using the methodology of (10) regarding the design of interventions. It includes the following steps: a) definition of the problem; b) characteristics of the problem; c) definition of the intervention; d) characterization of the intervention; e) validation of the intervention by experts who validated the understanding of the intervention based on the theoretical conceptualization and the operationalization of the activities in the proposed sessions; f) pilot test of the implementation of the intervention.

For the validation of the intervention, the sample consisted of eight experts in surgical oncology who reviewed the proposed content and format for the implementation of the intervention.

The pilot implementation test included a sample of ten users who met the inclusion criteria to determine the instructional and predictive value of the intervention. The intervention was initially applied in a tertiary care hospital in Bogota, and the follow-up was done through home visits.

Participants completed the intervention in its entirety and filled out the scale of self-management behaviors before the intervention and at one month and two months after hospital discharge.

Instruments and measurement

For validation by the experts, an *ad hoc* sheet was prepared to rate the clarity, precision, comprehension, relevance, and pertinence of the proposed intervention and the content of the educational material.

In the pilot test with patients, the PIH (Partners in Health) instrument was used, which measures self-management behaviors and comprises the dimensions of self-management knowledge, with scores from 0 to a maximum of 16, physician/patient alliance, from 0 to a maximum of 32, symptom recognition, from 0 to 16, and coping, from 0 to 32 (11). The sum of minimum and maximum scores ranged from 0 to 96, the results being interpreted as higher scores implying greater self-management behaviors.

Finally, an *ad hoc* card was prepared to monitor the implementation of the intervention in terms of knowledge, understanding, satisfaction, and usefulness of the intervention, as well as the identified distractions or interruptions and the additional observations of the participants.

Data analysis

Content validation (12) of the main components of the intervention was carried out. The experts rated on a five-point Likert-type scale, where 1 is total disagreement and 5 is total agreement, the clarity,

accuracy, comprehension, relevance, and pertinence of the material's content. The grade attributed for each of the components was considered and, based on this, the weighted average of the options indicated in the Likert scale with a variation from 1 to 5 points, where 1=0; 2= 0.25; 3= 0.5; 4= 0.75 and 5=1. Averages greater than or equal to 0.8 were considered "highly adequate," between 0.5 and 0.79 "adequate," and below 0.5 "not adequate."

For the data analysis of the pilot test with patients, the SPSS v23 package was used.

For the comparison of the self-management behaviors variable, the Friedman Test was used. For significance (which allows establishing pretest differences concerning months 1 and 2), values of $p < 0.05$ were considered statistically significant. The follow-up components of the intervention were analyzed in percentages, according to the number of appraisals expressed by the participants.

In relation to ethical aspects, those related to informed consent, voluntary participation, and confidential handling of information were considered. They also had the endorsement of the Institutional Ethics Committee and the Research Ethics Committee of the Faculty of Nursing of the Universidad Nacional de Colombia in the session of September 11, 2017 – minute number 13, and the requirements demanded by the Standard 8430 of 1993 by which the scientific, technical, and administrative guidelines for health research in Colombia are established (13).

Results

The results obtained from (10) are described below:

- a. *Definition of the problem:* People with CRC need to develop self-management behaviors once they leave the health care institution after surgery.
- b. *Problem characteristics:* issues related to the determinants and levels that affect the state of health and that may be in the biopsychosocial, physical, psycho-behavioral, and social domains: 1) symptom management and activities of daily living; 2) knowledge and beliefs; 3) treatment adherence; 4) emotion and stress management; 5) decision making; 6) skills and abilities.
- c. *Definition of the intervention:* Program for Self-Management Training in Colorectal Cancer (PEACCR, by its acronym in Spanish), based on individual and family theory and taking up the process elements that include knowledge and beliefs, self-regulation, skills and abilities, and social facilitation.
- d. *Characterization of the intervention:* the intervention consists of five sessions, three face-to-face and two via telephone follow-up. Each session takes place at a specific time, according

to the phase of the surgical treatment, and with a specific objective (Table 1).

e. *Validation of the intervention through expert opinion:* experts indicate that the intervention meets the criteria of clarity, accuracy, comprehensibility, relevance, and pertinence (Table 2).

Table 1. PEACCR scheme

Session		Moment-process in which it is carried out	Objective	Duration
1	Knowledge and beliefs before and during surgery	Weeks 1 and 2 after surgery	To generate a space for getting to know people in the process of caring for their health condition and to explore beliefs, expectations, and the generation of a goal plan.	60 minutes
2	Self-regulation, skills, and abilities Inpatient (hospitalization) and outpatient services	Weeks 2-3 Individual approach	To generate an action plan for goal setting, self-monitoring, and reflective thinking regarding the health condition. Indications on basic health condition care: diet and nutrition, exercise, and activities of daily living.	60 minutes
3	Social facilitation Postoperative control and outpatient clinic	Weeks 3-4	To generate a space that allows recognizing the social facilitation that the person has for the self-management of his/her health.	60 minutes
4	Follow-up 1 Postoperative control and outpatient clinic	Weeks 5-6 Individual	Follow-up of the self-management plan and evaluation of compliance with goals. Self-regulation support, skills, and abilities.	20-30 minutes
5	Follow-up 2 Postoperative control and outpatient clinic	Weeks 7-8	Follow-up on goals achievement.	20-30 minutes

Note: According to the access conditions, there will be a telephone line and WhatsApp to answer questions and guide patients and caregivers.

Source: prepared by the authors.

Table 2. Content validation by experts

Sessions	Clarity	Precision	Comprehension	Relevance	Pertinence
Knowledge and beliefs	0.80	0.83	0.83	0.88	0.80
Self-regulation, skills, and abilities	0.83	0.80	0.83	0.80	0.80
Social facilitation	0.86	0.86	0.91	0.88	0.88
Self-management plan follow-up	0.72	0.86	0.88	0.91	0.88
Self-management plan follow-up	0.80	0.86	0.94	0.88	0.88

Source: prepared by the authors.

As recommendations of the experts, it is suggested to a) provide a demonstration workshop to patients who leave with colostomies in the presence of the family; 2) provide education on nutrition and management of alarm signs and symptoms; 3) use various means of follow-up communication.

- f) *Pilot test of intervention implementation:* the implementation of the intervention was carried out with ten patients diagnosed with adenocarcinoma of the colon, colorectal, or rectum, who were admitted to an oncology care center in Bogotá, five of whom were female. Ages ranged from 40 to 87 years; most were CRC stage IIIB; the type of treatment received was total colectomy, tumor resection, proctosigmoidectomy, or sigmoidectomy. Most have a home occupation, with low levels of schooling and socioeconomic stratum 3; of the 10 participants, 6 had a colostomy (Table 3).

Table 3. Characteristics of the Participants in the Pilot Intervention Study

Participant	Level of Education	Occupation	Socioeconomic stratum	Stage	Type of treatment
1. Male, 60 years old, married	Low	Self-employed	2	IIIB	Total colectomy
2. Female, 63 years old, married	Average	Housewife	3	IIA	Anterior tumor resection
3. Female, 87 years old, married	Low	Housewife	3	III	Anterior tumor resection
4. Female, 55 years old, common-law marriage	Average	Housewife	2	IIIB	Total colectomy
5. Male, 69 years old, married	Average	Housewife	3	IIA	Proctosigmoidectomy
6. Male, 40 years old, single	High	Employed	2	II	Anterior rectal resection
7. Female, 48 years old, separated	High	Self-employed	3	IIIB	Sigmoidectomy and bypass
8. Male, 62 years old, married	Low	Self-employed	2	IIIB	Colectomy
9. Female, 66 years old, common-law marriage	Low	Retired	2	IIIB	Hemicolectomy y anastomosis
10. Male, 63 years old, married	Low	Self-employed	3	IIA	Sigmoidectomy

Source: prepared by the authors.

In terms of self-management behaviors, a mean of 67.4 was reported at the beginning of the intervention (pretest). At month 1, an increase in these behaviors is identified (mean 78.6, SD 10.1), as well as in the second month (mean 86.6, SD 8.1), with statistically significant differences between the periods (p 0.000).

In the analysis by dimensions, an increase in values was identified in all of them, both in months 1 and 2, and with statistical significance in self-management knowledge (p 0.003), coping (p 0.035), and health personnel-patient alliance (p 0.045) (Table 4).

Table 4. Self-management Behaviors in the Pretest, Month 1, and Month 2 of the Intervention

Variable	Possible scores	Time	Average	DS	Min	Max	p value*
Self-management behaviors	0 to 96	Pretest	67.4	17.5	37	92	0.002
		Month 1	78.6	10.1	56	93	
		Month 2	86.6	8.1	74	96	
Coping	0 to 32	Pretest	23.0	9.0	8	32	0.035
		Month 1	25.0	5.4	17	31	
		Month 2	28.9	3.1	24	32	
Knowledge in self-management	0 to 16	Pretest	8.5	4.1	2	16	0.003
		Month 1	10.8	3.5	5	16	
		Month 2	12.9	2.2	10	16	
Health personnel-patient alliance	0 to 32	Pretest	23.5	5.6	16	32	0.045
		Month 1	28.7	3.8	20	32	
		Month 2	29.6	3.5	23	32	
Symptom recognition	0 to 16	Pretest	12.4	4.8	2	16	0.291
		Month 1	14.1	1.7	11	16	
		Month 2	15.2	0.8	14	16	

* Friedman Test. Statistical Significance p 0.005

Source: prepared by the authors.

Regarding the aspects evaluated during the implementation of the intervention, 100 % of the participants reported that a high level of knowledge was obtained, so they have a high level of impression, satisfaction with the proposed format, understanding, and perceive the usefulness of the information provided. Among the distractors, in the health care institution, the procedures to be carried out for authorizations and medical appointments, and in the home, other tasks that arise daily, such as childcare and household responsibilities, are mentioned. The 20 % suggest more time for the sessions and accompaniment by the institution once they have left.

Discussion

The study contributes to the design of an intervention that takes up approaches from the theory of individual and family self-management, not only through the integration of aspects of instruction, education, and follow-up but also by strengthening the role of human talent as “facilitator” and guide of processes that the patient must consolidate. The person with a health condition is assigned an active and leading role, which implies making decisions and developing skills based on the knowledge and beliefs derived from the context in which he/she is immersed.

Regarding how the intervention is provided, i.e., the number of sessions and the time allocated for them, acceptability is identified by the participants, with high satisfaction, comprehensibility, and perceived usefulness. The program offers a format that highlights the patient’s needs under the person-centered care model (14) and includes a self-management plan based on the goals and challenges that the patient reflects upon. Although the instruction and information component is essential, the aim is to transcend to other issues, which will probably have a greater impact on the user in terms of reincorporation into daily activities and personal perspective. This scheme contrasts with interventions carried out at the local level, which maintain an outline towards conventional education and follow-up in the Colombian context with chronic patients (15,16).

Regarding the efficacy of the intervention on the outcome variable, the study reported an increase in self-management behaviors and the dimensions of coping health personnel-patient alliance, and knowledge of the disease. These findings are consistent with those reported in other studies with chronic patients (17,18), in which the approach to specific conditions predominates in relation to information, medication administration, symptom management, improvement of self-regulation and social support.

Considering the timing of the intervention to achieve an impact on self-management outcomes, this pilot is close to the proposal of (19), who generated a six-week asynchronous online self-management program for chronic diseases (arthritis, asthma, cancer, COPD, diabetes, heart disease, and mental health conditions). However, the effects were obtained only up to six and twelve months after the intervention; in contrast, with prostate cancer patients, the interventions were effective at eight months due to the direct contact of the health care team and monitoring (20) to achieve self-management behavior.

According to (21), self-management interventions provide the necessary training for informed decision-making (22) for initial treatment and to assist in long-term symptom management in cancer survivors (21). This pilot study was able to recognize that

satisfaction with health care was significant from the beginning of the intervention. It should be noted that the aim was to consolidate a comprehensive strategy that would be easy to apply and feasible to replicate in local health services, where the postoperative follow-up scheme is limited. This coincides with what Carrillo et al. stated when they affirmed that the educational intervention carried out by nursing personnel with caregivers of adults with cancer undergoing coordinated surgery, which includes assessment upon admission to the institution, delivery of educational material, face-to-face instruction and specific information, demonstrative workshop, and telephone follow-up, increases home care competence in its six dimensions and decreases caregiver overload (23). However, online intervention studies (24) should be designed to provide a feasible and effective alternative to in-person support, with diversity in social and cultural aspects.

Regarding information, this should be precise, simple, and short, including aspects such as self-management, coping, psycho-educational support, lifestyles, body image, and mental health (25), on issues such as depression, fatigue, and distress during treatment (26) in cancer patients (27). Skills and abilities require personalized instruction, simulation, and follow-up (28). The meta-analysis by Medina et al. allowed grouping the assessment of the efficacy of self-management in relation to medication compliance, lifestyle changes, and modification of clinical variables (29), key variables to be taken into account in future intervention studies.

This program also indicates the need for nurses —trained in innovative roles— who can provide ongoing support and feedback to participants using available support networks (30). For example, the provision of nurse navigators or case managers —who coordinate care and access to information— has demonstrated benefits in cancer patients who present emotional symptoms during diagnosis and treatment related to the impact on quality of life and psychosocial problems, which from the nurse's role can be addressed, developing expected competencies to demonstrate results in care that will improve the quality of care and clinical outcomes (31,32). In this sense, effective implementation implies several challenges, for which it is necessary to visualize people in their context, considering not only their needs (33) but also the resources they possess and have acquired during their lives. Hence, the educational role is essential to address self-management programs (34), with nurse navigators that facilitate the process of health recovery (35) from a human perspective.

According to (36), people with cancer have poor self-management practices. And in this intervention, factors of self-management behaviors were identified that might, in future studies, be related to the quality of life, so it is suggested to continue researching and deepening to identify other factors associated with self-management in these people with CRC.

The present study confirms the importance and relevance of developing self-management programs in the care of cancer patients. The results may contribute to a better understanding of the self-management approach as a proximal health outcome indicator. It will serve as a reference for estimating effect and sample size calculations in randomized controlled clinical trials. On the other hand, contextual factors that may affect the successful implementation of this program to enrich follow-up approaches in the routine care of outpatients with complex health conditions are glimpsed.

It is also necessary to explore the effects on service utilization and to determine whether the benefits obtained from participation in a self-management program can be sustained over time. Likewise, it is necessary to design recruitment strategies to minimize attrition rates and ensure the participation and motivation of more people to analyze these results in other Latin American contexts (37).

Conclusions

The designed and validated intervention shows promising preliminary results in increasing patients with colon and rectal cancer self-management behaviors. The proposed scheme is highly acceptable to the participants, provides conceptual elements derived from a mid-range theory, as well as procedural aspects to determine effectiveness and impact in controlled clinical trials, intending to implement and replicate it in outpatient follow-up phases in cancer patients, where the role of the health worker allows guiding the decision making of patients in health services.

Conflict of interest: None declared.

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