International Egyptian Journal of Nursing Sciences and Research (IEJNSR)

Original Article

Effect of a FOCUS-PDCA Procedure on Clinical Outcomes and Quality of Life Among Egyptian Patients with Colorectal Cancer Undergoing Colostomy: A Randomized Control Trial

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ABSTRACT

Background: Colorectal cancer has become one of the most common types of cancer that affect patients' self-care ability and quality of life. **The aim** of this study was to evaluate the effect of implementing FOCUS-PDCA Procedure on clinical outcomes and quality of life among Egyptian patients with colorectal cancer undergoing colostomy. **Design**: A randomized controlled trial was conducted on sample of 100 patients with colorectal cancer were in the hospital to undergo a colostomy. Participants were randomized into an intervention and control group (n= 50/group). **Measurements**: **(a)** A Structured Interview Questionnaire**; (b)** Colostomy Patients' Clinical Outcomes Assessment, and **(c)** Stoma Quality of Life Questionnaires were used to assess the effect of the FOCUS-PDCA Procedure on their clinical outcomes and quality of life. **Results**: Among the subjects n=100, (ANOVA) revealed a statistically significant difference between study and control groups in relation to time of intervention in self-care ability includes; Self – Care knowledge, Self-care skills, Self-care attitude, and quality of life which were higher in study group than control as (p=≤.001). **Conclusion**: FOCUS-PDCA Procedure was effective in improving self-care ability and quality of life. **Recommendations:** application of A FOCUS-PDCA Procedure on different setting on patients with colorectal cancer undergoing colostomy**.**

Keywords*:* colorectal cancer, colostomy, clinical outcomes, FOCUS-PDCA, quality of life**.**

Introduction

Globally, colorectal cancer has become one of the most leading type of cancer. It affects more than 10.0% of the world population **(Xi & Xu, 2021) & (Siegel et al., 2023).** Its causes include many factors such as an unhealthy diet, colon disease history, inherited family colon diseases and some other biochemical or environmental factors. Low colorectal cancer is the main type of colorectal cancer **(Meza, 2023)**. Regarding

colorectal cancer treatment, surgical interventions are one of the primary methods of managing this malady. The most common surgeries performed are colon resection with anastomosis, abdominoperineal resection, and colectomy (colon removal) with colostomy which is the most common method **(Medscape.com, 2019).** However, there are several therapies used in the therapeutic process: Chemotherapy and radiotherapy, which are used to prolong life, prevent recurrence and forestall any additional disease development. Collectively three approaches help to assuage symptoms and discomfort **(National Cancer Institute, 2020).**

The primary method of treatment in this study is surgical intervention. What follows is a brief description of the procedure. When a portion of the colon or rectum is removed, the healthy parts can be connected to the large intestine which will allow for normal elimination. However, sometimes reconnection of the intestines is not possible at the time of the surgery **(Cleveland Clinic, 2022).** In this case, the colon can be connected to an opening in the abdominal call a stoma. The stoma appears on the outside of the abdominal wall, and bowel evacuation occurs through this newly created opening. The majority of patients with colorectal cancer may need a temporarily colostomy, until the colon or rectum recovers from surgery **(Canadian Cancer Society, 2021).**

Nevertheless, after healing is evident, usually 6 to 8 weeks, the end of the colon can be reconnected and the stoma is removed or closed. In instances where this procedure cannot be completed, a permanent colostomy is necessary and the person will continue bowel evacuation through the stoma. Fortunately, most people experience the reconnection—about 26% versus 7 % of individuals who might need a permanent stoma. Even though the latter outcome is not desired, it saves lives **(Mesri et al., 2022) & (Johns Hopkins Medicine, 2022).**

Best practices suggest that colostomy surgery helps to prolong live, improve productivity, and enhance the quality of life. These procedures have complex physical, psychological, social, and spiritual issues that must be considered and addressed in a culturally appropriate manner. Sensitivity should be given to lifestyle changes, attitudinal shifts, and other concerns that are evident among patients and their families **(Zewude et al., 2021).**

To help assure positive clinical outcomes, all health professionals should consider teaching the patient and family members about self-care **(Kluwer, 2017).** When patients and caregivers are informed about the procedure and the care of the patient, outcomes are more likely to be positive. Examples of teaching topics include stoma care skills, support counseling, nutrition and dietary habits, management of complications, skin care, and the need for follow-up with appointments **(Tuominen et al., 2021)**.

Self-care is one of the main essential aspects of improved well-being. In an effort to expand self-care the implementation of the Plan, Do, Check Action (PDCA) strategy has proved to be

effective, and is best when used with multidisciplinary teams. The FOCUS-PDCA procedure is continuation and enhancement of the PDCA cycle. Here is this delineation: F (find the problem); O (organize); C (clarify); U(understand); and S (select). The aim of the procedure is to highlight all aspects of the process, and given particular attention to all aspects of the assessment procedure **(American Society for Quality, 2019), (Sun et al., 2021) (Mind Tools, 2022).** Because colostomies cause biopsychosocial problems that can negatively affect the person's overall life style, including the quality of life (QoL), self-care and overall wellbeing **(Ayaz-Alkaya, 2018), (Ramamoorthy et al., 2020) (Stavropoulou et al., 2021).** All nurses and health care providers should develop culturally appropriate patient-focused programs, which help them to increase their health literacy, practice, independence. Individuals with colostomies can life a productive and engaged life, and achieve a high standard of living (**Loan et al., 2018), (Hernes and Ott, 2018) & (Kaihlanen et al., 2020).**

Aim of the study

The aim of the study was to evaluate the effect of a FOCUS-PDCA procedure on clinical outcomes and quality of life among Egyptian patients with colorectal cancer undergoing colostomy.

Research hypothesis:

To fulfill the study's aim, the following research hypotheses were tested.

H1; The application of FOCUS-PDCA Procedure will have improved self- care among adult patients with colostomy when compared with patients who did not receive intervention.

H2; The application of FOCUS-PDCA Procedure will decrease the level of peri-stomal skin complications among adult patients with colostomy, when compared with patients who did not receive intervention.

H3; The application of FOCUS-PDCA Procedure will achieve higher total quality of life scores among adult patients with colostomy, when compared with patients who did not receive intervention.

Operational Definition

The following operational definitions selected to be used in this study:

FOCU- PDCA procedure: There are nine phases involved in implementing the FOCUS-PDCA procedure: five FOCUS steps and four PDCA cycles. The FOCUS procedure's goal is to locate possible issues. Attaining continual quality improvement for patients is the primary goal of PDCA.

Subjects and method

Research design:

This study used a randomized controlled trial (RCT) design. The effect of the FOCUS-PDCA Procedure on clinical outcomes and quality of life scores among adult patients with colostomy was assessed in such study.

Study Setting:

The study was carried out in Tanta Cancer Institute in Tanta, Egypt, as well as the Tanta University Hospital's oncology and nuclear medicine departments.The hospital is divided into two floors for men and women. Each floor has five wards, each of which has six beds hanging. The two units can accommodate a total of thirty beds.

Sampling

The study's sample included one hundred male and female patients who were randomly allocated to one of two groups based on their colorectal cancer diagnosis and scheduled for colostomies. Adults between the ages of 20 - 60, were able to sign an informed consent form indicating their agreement of the study, able to converse, and report practicing self-care.

Sample size equation:

$$n = \frac{N \times P (1-P)}{(N-1 \times (d2 / z2) + P (1-P)}$$

n= sample size

N= total society size

D= error percentage (0,05)

Z= the correspond stander class of significant 95% (1, 69)

P= percentage of availability of the objectivity = (0, 1)

Sample size was calculated at 95% confident power of the study using Steven Timpsona.

Allocation into the groups

Patients were randomly allocated either to the study group or to the control group. Randomization was done with 1:1 ratio (i.e., 50 study group: 50 control group). In addition, Randomization was done using a closed envelope system, which consisted of envelops with either S or C written on the inside of the envelope. Each patient was asked to select one of the envelops. Those patients who selected the envelope with the letter S were assigned to the study group, while patients who selected the envelop with letter C were placed in the control group and received the usual hospital-based treatment.

Tools of data collection:

Three tools were used to collect data as follow;

Tool (1) Structured Interview Questionnaire

This tool adopted from **(SukhpalKaur, 2013),** translated into Arabic and consisted of two parts; **part one** included participants' socio-demographic features such as age, sex, marital status, educational attainment, employment situation, and marital status. Descriptive statistics was used to analyses this data. **The second part** of the tool addressed **Problems experienced by patients with Colostomy;** This part of the tool consisted of 12 items. The study included postoperative patient follow-up data collection sheet which included (physical problems (5) items, sexual problems (5) items, and nutritional problems (2) items). **Scoring system:** Each item was observed, categorized, and recorded as, presence of the problems which equaled one, while absence of the problem equaled zero with total score of twelve.

Tool(II):Colostomy Patients' Clinical Outcomes Assessment Tool:

this tool was used to evaluate the effect of implementing the FOCUS-PDCA Procedure to determine the patients` clinical outcomes. It consisted of two parts;

Part one: The peri-stomal skin DET Assessment

The assessment tool was adopted from **(Martins et al., 2015)**, and used to assess the extent of severity of the peristomal skin complications. This evaluation consisted of three items that are associated with the degree of discoloration, erosion, and tissue overgrowth (DET). The items related three scores were recorded expressed as percentages, and then divided into severity categories as shown below;

Mild = DET < 4

Moderate = DET ≥ 4 < 7

Severe = DET ≥ 7

Part two: Self-Care Ability Checklist for Colostomy Patients:

This 25 items tool was adopted from **Rivet, EB (2019)** to assess self-care knowledge (11), self-care skills (8), and self-care attitude (6). Scoring system, Items were scored using an ordinal scale of 0 to 4 points, where a score 0 indicated a low level of self-care and 4 indicated a high level of self- care. The 25 scored items generated a cumulative score ranging from 0 to 100 points, with higher scores indicating higher levels of self-care.

Tool (III): The "Stoma Quality of Life (QOL) Questionnaire

The Stoma-QOL questionnaire is a patient self -reported outcome (PRO) used to measure QOL in patients with an ileostomy or colostomy. The tool was adopted from Lai et al. (2018). The questionnaire consisted of 20 items with four domains. Self-esteem and Self-image, Relation with Family and Friends, Relation with Sleep and Fatigue and Ostomy Device Functioning insecurities. **Scoring system:** the patients h**ad the opinion of determining the level of QOL as** Always (1), Sometimes (2), Seldom (3) & not at all (4)

The total score is calculated by combining the values of each question, resulting in an upper limit of 80 and a lowest number of 20. The lower the score (20-63), the lower quality of life level, while indicated amore satisfactory level of (64-80).

Validity and Reliability

All research instruments were examined by a group of five health professionals with extensive experience in the field of medical- surgical nursing. All of the panelist are members of the faculty of nursing at kafrelsheikh and Tanta university. They examined the tools for relevancy, clarity, comprehensiveness, and applicability of the tools for the sample in the study. According to their findings, a minor modification was done. Reliability was done using Cronbach's alpha coefficient test for the Stoma Care QOL Scale which has a 0.90 (95% CI 0.88-0.92). Rasch analysis supported the viability of the Stoma Care QOL Scale Questionnaire and showed acceptable

goodness-of-fit. reliability for the peristomal skin assessment was 0.89**.**

Ethical considerations

The Scientific Ethical Committee of Tanta University's Faculty of Nursing granted the ethical permission, and approval reference number (129) was provided. The patients were informed about the goal of the study and gave their informed consent to take part in it. Every participant was made aware of his/her right to discontinue the study at any moment and without explanation. By using a coding method, information secrecy and anonymity were guaranteed. Respect was shown for ethics, morals, culture, and beliefs.

Pilot study

In order to verify the feasibility of the study and the study tool for data collection, test its practicality and clarity, estimate the time required to complete the study, and look into issues pertaining to the research design, ten participants who met the same inclusion criteria participated in a pilot study. The research tool didn't need to be changed based on comments from the pilot study. The entire study sample included patients who took part in the pilot study.

Procedure

Data were collected over a five -month period and in four phases. The phases are described below:

Phase One: Assessment phase: During the initial phase of the research, the administered the Tool I, that has two parts: The structured interview and Problems Experienced by Patients with Colostomy (PEPC). After the Structured Interview was completed, it was determined if the inclusion criteria for the study was met. If the criteria were met, then data collection continued, and the patient was invited to join the study. At this point, the second part of Tool 1 was administered, which is the PEPC. It is used to assess problems experienced by the patients at three time points: One day after surgery, one week later, and then one month after the surgery. Each data collection time point took approximately 30 minutes.

The second tool, **Colostomy Patients Clinical Outcome Assessment Tool also has two parts. (1) The Peri-stomal skin DET Assessment** is designed to evaluate the degree of severity associated with a peristomal skin problem. The tool was administered twice: One week after surgery and one month after surgery for approximately 30 minutes. The second part of the tool was the **(2) Self-care Ability Checklist for Colostomy Patients.** It was used to document the patients' self-care knowledge, self-care skills, and self-care attitude. It was administered at three time points: First day after surgery, one week later, and one month after surgery for approximately 30 minutes.

Phase Two: Planning phase for Patient Teaching

The results of phase one and recommended procedures as stated in the scientific literature served as the foundation for this phase's formulation. The purpose of phase two was to develop culturally appropriate teaching materials for patients. The materials included instructions

about **Preoperative nursing care,** which involved preoperative assessment, bowel preparation and the self-management of complications in the preoperative period. Patients were also instructed about **Interoperative procedures** that would help them to have a basic knowledge about the surgical procedure. The components of this teaching included prophylaxis (medications before surgery), skin preparation, surgical techniques that will be used during the operation, and abdominal wall closure. The final teaching phase is **Patient-Centered Postoperative care**. It involves surgical wound care, and the continued care of the colostomy, and implications for diet and nutrition, sexual health, and exercise.

Phase Three: Implementation of a Structured Interventions for Patient Health Teaching

This phase consisted of five sessions lasting from 20 to 30 minutes during the patients' hospitalization, were delivered in Arabic, and at a level of comprehension of each patient. At the beginning of the first session, an orientation to the purpose of the study, the methods that were used, and content related general information about colostomy care. The second and third sessions focused on self-care as related to the impending surgical procedure, colostomy maintenance and other topics generated by the patients. Each of the two sessions started with a brief summary of the topics that were covered in the prior session, along with an explanation of the goals for the existing one.

Also, sessions four and five occurred after the surgery and the colostomy had been created. The contents of these two sessions consisted of face-to-face teaching regarding self-care: diet, nutrition, exercise, cleaning, potential complications, and continuity of care. Emphasis was placed on the use of lavender essential oils for colostomy care. See Appendix B. Session five was focused on reinforming content in the four sessions and responding to questions that the patients asked. The sessions conclude with a discussion of the contents of a booklet that contained a detailed description of self-care, including how to change and maintain the pouch. These booklets were distributed to all patients in the study at the end of session five.

The implementation of the FOCUS-PDCA procedure follow as sequence that is composed of 9 steps, encompassing 5 FOCUS steps and 4 PDCA cycles. The purpose of the FOCUS procedure is to anticipate possible problems, and achieve the its quality-of-life that is possible for the person.

Phase Four: Evaluation phase

Patients who participated in the study were evaluated using a SIQ at three data points: Baseline, seven days and one month following surgery, respectively. The SIQ was followed by Tool II (CPCOA) and tool III (QOL) after one week, and one month of the surgical procedure.

Statistical analysis

The obtained data were organized, tabulated and scientifically analyzed using SPSS program

(Statistical Package for the Social Sciences, version 26, SPSS Inc. Chicago, IL, USA). For numerical data, the range, mean and standard deviation were computed. comparison between means of two groups of parametric data of independent samples, t-test was used. Repeated measures ANOVA used to compare between groups by time.

RESULTS

Subjects' characteristics

Table (1) reveals that more than half (52% &58%) of groups ages ranged from 41-60 and from 31-40 years among the study and control group consequently, about two thirds of control group (60%) were married female resided in rural area with age ranged from 3140 years. regarding educational levels the result indicates that (44% %& 30 %) of the study and control group consequently were not able to read and write, while only (3 %) of the study subjects were having high academic level. Regarding work, the majority of both groups were house wife (46% &70%) in the study and control group respectively.

Table (2) displays that there is no statistically significant difference between the two groups in the first day in relation to Self – Care knowledge score, while there is a highly statistically significant difference between the same groups in first week and first month as ((P<0.001).

Table (3) demonstrates that; in relation to self-care scores, In the first week and first month, there is a highly statistically significant difference between the study and control groups as ((P<0.001). while there is no statistically significant difference between the same groups in the first day.

According to table (4), there is a highly significant difference in self-care attitude scores between the study and control groups in the first week and first month (F= 17.806 & p= <0.001) & (F= 9.020 & p= <0.001).

Table (5) indicates that, one month after intervention, there was a highly statistically significant difference between the study group and the control group in terms of the severity of peristomal skin problems. However, there was no statistically significant difference in the control group's first week and first month's levels of peristomal skin problems severity.

The data in table (6) directly address the hypothesis of the study**:** The application of FOCUS-PDCA Procedure will achieve higher total quality of life scores among colostomy patients. Between the study and control groups, there was a significant statistical difference in the mean scores for overall quality of life with regard to time as (F= 27.163 & p= 0.001) & (F= 22.093 & p= 0.001), respectively. ANOVA test was accustomed to answer the third research hypothesis through testing the change in means over the time between groups.

Table1: Number and distribution of the general characteristics of the study sample (N=100)

Socio-demographic data	Study group (50)		Control group (50)		Chi – Square / Fisher's exact test	
	n	%	n	%	X^2	P
Age (Years)						
20-30	6	12.0	6	12.0		
31 – 40	18	36.0	29	58.0		
41-60	26	52.0	15	30.0	5.526	0.063
Gender						
Male	24	48.0	20	40.0		
Female	26	52.0	30	60.0	0.649	0.420
Marital Status						
Single	8	16.0	4	8.0		
Married	30	60.0	33	66.0		
Divorced	10	20.0	8	16.0		
Widow	2	4.0	5	10.0	2.984	0.394
Occupation						
Employee	8	16.0	5	10.0		
Worker	7	14.0	3	6.0		
Free worker	12	24.0	7	14.0		
Housewife	23	46.0	35	70.0	6.091	0.107
Residence						
Rural	30	60.0	31	62.0		
Urban	20	40.0	19	38.0	0.042	0.838
Educational Level						
Cannot read or write	22	44.0	15	30.0		
Read and write	5	10.0	9	18.0		
Primary	5	10.0	7	14.0		
Intermediate	15	30.0	19	38.0		
Academic	3	6.0	0	0.0	6.271	0.180

Table 2. Comparison of Self – Care knowledge score between study and control groups

	Study group		Control group		Student's T – Test	
	Mean ±SD	Range	Mean ±SD	Range	T	P
1st Day	27.5 ±11.1	3 – 43	30.8 ±8.2	11 – 44	1.720	0.089
1st Week	40.5 ±2.2	34 – 44	32.6 ±7.5	14 – 43	7.147	<0.001**
1st Month	40.2 ±1.9	36 – 44	36.7 ±2.4	31 – 42	8.132	<0.001**
Oneway ANOVA [F / P]	F = 62.733, P<0.001**		F = 10.611, P<0.001**			

Table 3. Comparison of Self – Care skills score between study and control groups

	Study group		Control group		Student's T – Test	
	Mean ±SD	Range	Mean ±SD	Range	T	P
1st Day	19.6 ±9.1	0 – 32	21.9 ±7.9	4 – 32	1.349	0.180
1st Week	28.6 ±2.3	21 – 32	22.1 ±6.2	10 – 31	6.758	<0.001**
1st Month	30.4 ±1.5	24 – 32	28.1 ±1.9	23 – 32	6.712	<0.001**
One way ANOVA [F / P]	F = 55.583, P<0.001**		F = 17.825, P<0.001**			

Table 4. Comparison of Self – Care Attitude score between study and control groups

Table 4. Comparison of Self – Care Attitude score between study and control groups						
	Study group		Control group		Student's T – Test	
	Mean ±SD	Range	Mean ±SD	Range	T	P
1st Day	20.1 ±3.6	12 – 24	19.3 ±1.6	12 – 24	1.435	0.154
1st Week	21.9 ±1.6	18 – 24	20.9 ±2.8	12 – 24	2.192	0.030*
1st Month	22.9 ±1.2	18 – 24	21.4 ±3.1	16 – 24	3.190	0.002*
Oneway ANOVA [F / P]	F = 17.806, P<0.001**		F = 9.020, P<0.001**			

Table 5. Comparison of peristomal skin complications score between study and control groups

Table 5. Comparison of Peristomal Skin complications score between study and control groups						
	Study group		Control group		Student's T – Test	
	Mean ±SD	Range	Mean ±SD	Range	T	P
1st Week	5.8 ±2.7	1 – 11	6.0 ±2.9	1 – 11	0.308	0.759
1st Month	2.9 ±1.4	0 – 5	5.7 ±2.1	1 – 9	7.866	<0.001**
Student's T – Test [T / P]	T = 6.742, P<0.001**		T = 0.592, P=0.559			

Table 6. Comparison of Stoma QOL score between study and control groups

Table 6. Comparison of Stoma QOL score between study and control groups						
	Study group		Control group		Student's T – Test	
	Mean ±SD	Range	Mean ±SD	Range	T	P
1st Day	36.9 ±16.9	20 – 80	24.0 ±9.1	15 – 47	4.728	<0.001**
1st Week	49.2 ±17.2	20 – 77	33.5 ±15.1	20 – 62	4.860	<0.001**
1st Month	60.0 ±12.5	31 – 80	41.3 ±14.1	20 – 62	7.019	<0.001**
Oneway ANOVA [F / P]	F =27.163, P<0.001**		F = 22.093, P<0.001**			

Discussion

The main objective of the existing research was to evaluate the effect of FOCUS-PDCA Procedure on clinical outcomes and quality of life among colorectal cancer patients' undergoing colostomy. The results of the study supported the study hypothesis that the application of FOCUS-PDCA Procedure had a positive effect on self- care ability among colostomy patients, it decreased the level of peri-stomal skin complications and achieved higher total quality of life scores among the study subjects.

On investigating sociodemographic data, our study showed that more than have of study groups were male, their ages ranged from 41-60 years, 31-40 years as (52%) and (58%) for the study and control group consequently. These results are supported by the study`s outcomes of **(Aishah, Karen, &Ian, 2022)**, (**Roydhouse & Wilson, 2017) & (Alenezi et al., 2022)** whom studied "Ostomy-related problems and their impact on quality of life of Saudi ostomate patients: A mixed-methods study" and reported that Most of the participants were male (56%) in the same range of age.

Regarding the self-care ability among the studied subjects, our study results revealed that the self-care ability in form of knowledge, skills and attitude of the study group increased in first day one week and one month consequently. In addition, there is a highly statistically significant difference in Levels of Self-care ability in 1st week and 1st month in the study group compared with control group as (P<0.001).

This study is supported by the study of **(Jin et al., 2021)** who conducted a study on the "Impact of FOCUS-PDCA procedure on improving self-care ability of patients undergoing colostomy for rectal cancer" and found that, following the application of FOCUS-PDCA, the self-care ability of 80 patients with colostomies due to rectal cancer increased by 21.06%, from 39.09 to 60.15 points. Patients' self-care ability rose from 61.50 to 83.13 points one month after FOCUS-PDCA was implemented; this was a 21.63% increase, and the difference was statistically significant (P<0.01). From my point of view, after patients have been

received education regarding the disease and how to care with their colostomies, this reflected positively on their self-caring ability and quality of life.

On investigating physical, problems experienced by the subjects; one third of the study subjects complained of a disturbed sleep pattern brought on by pain or discomfort, a fear of leaks, and a failure to adapt everyday activities. These outcomes align with the research findings published by **(Stavropoulou et al., 2021)** whom concluded in their results " Physical, Notional And Sexual Problems Experienced By The Patients With Colostomy /Ileostomy: A Qualitative Stud" that one third on the subjects reported problems related to stoma such as; altered sleep pattern related to fear of leakage, pain or discomfort, negative change in daily living activity in addition to nutritional and sexual related problems because of presence of stoma. From my point of view, presence of stoma, wound or any abnormal and unusual procedure can cause pain, disturbed sleep, fear from leakage and even removal of the stoma, all these can affect negatively on overall health, not only daily living especially in female more than male patients.

Regarding quality of life, our study demonstrated that there is highly statistical significance in QOL scores among study group in first week and first month as **(P<0.01.** Additionally, the current study's findings are consistent with (**Mandal et al., (2021) & (Chattu et al., 2020)** whom displayed that the use of the PDCA procedure improved all domains of quality of life as (p=0.01), according to "A Randomized Study to Evaluate Effectiveness of Verbal versus Written Peri-operative Information Developed by Quality Improvement (QI) Module for Assessing Patient Satisfaction and Quality of Life. From my point of view, education in general regarding any disease and how to care with it can help majority of people to act in heaty manner leading to improve quality of life and overall health.

Conclusion and recommendations

In conclusion, this research revealed that FOCUS-PDCA Procedure could statistically improve self-care ability among patients aged 20-60 years, diagnosed with colorectal cancer and have colostomy. It also demonstrated that the procedure had proved positive effects in increasing quality of life scores among the study subjects. The current study recommended that it is essential to implement FOUCUS-PDCA procedure among patients with colorectal cancer to help them to overcome self-care disability and improve their overall quality of life.

Implications for nursing practice

FOCUS-PDCA Procedure is considered one of the most important interventions that should be emphasized by the nurse in order to improve clinical outcomes and quality of life. These findings are in agreement with **(Jin et al., 2021) &** (**Mandal et al., (2021)** whom emphasized that FOCUS-PDCA procedure enhanced self-care ability and quality of life. In addition, the current study findings also indicated that application of

FOCUS-PDCA Procedure had a positive impact on improving clinical outcomes and quality of life among Egyptian patients with colorectal cancer undergoing colostomy.

Limitations of the study

Although there were significant differences between fatigue levels in relation to four time points, the researcher did not assess the family psychological support and /or if patients are included in any support group during the time at which the study was conducted. Family psychological support and /or included in other support groups could be an extraneous factor that interfere with improving clinical outcomes and quality of life. For instance, when patients receive psychological support during the treatment period, it improves their psychological state, which may play a role in enhancing living quality and clinical outcomes.

Conflict of interest

Conflicts of interest are not disclosed by the researchers.

Acknowledgements

The patients and those who took part in and assisted in the completion of this study are all appreciated by the authors.

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