Effect of Implementing Nursing Care Protocol on Daily Life Burden among Patients with Inflammatory Bowel Diseases

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Abstract:

Background: Inflammatory bowel diseases [IBDs] are chronic inflammatory disorders that affect adversely on various aspects of daily life. Therefore, a protocol of nursing care is crucial, taking into account IBD-related disability and over all daily-life burden. **Aim of the study:** This study aimed to evaluate the effect of implementing a protocol of nursing care on daily life burden of patients with inflammatory bowel diseases**. Design and Setting:** The present study applied a quasi-experimental research design. The study was operated in Outpatient Rheumatology Clinic at Damanhour National Medical Institute in Elbehira governorate, Egypt. **Subjects:** A purposive sample of 70 adult patients admitted to the above-stated settings. The study subjects were divided randomly into two equal groups; study and control; each group comprised of (35) patients. **Tools:** two tools were used for data collection, **Tool I:** The inflammatory bowel disease patient's socio demographic &clinical data assessment schedule, **Tool II:** The inflammatory bowel disease disk (IBDD). **Results:** it was observed that, there was a extremely statistically significant difference related to levels of their daily life burden pre and post-2 weeks of implementation of a care protocol, compared to the control group. **Conclusion and Recommendation:** Protocol of nursing care of patients with IBD had a crucial role in improving patients' compliance with therapeutic regimen which affects positively their daily life burden related disabilities. Also, it was recommended that pre-service training instructions should be supplied to the newly assigned nurses before undertaking autonomous responsibilities for IBD patients' care. In addition, established competencies fliers about care for IBD patients would be accessible to all staff nurses in medical departments and outpatient clinics.

Key words: Protocol of nursing care, Daily life burden, Inflammatory bowel diseases, Ulcerative colitis, Crohn's disease.

Introduction

Inflammatory bowel disease (IBD) is a scope of inflammatory disorders composes of Ulcerative colitis (UC) and Crohn's disease (CD), which are portrayed by chronic inflammation of the gastrointestinal tract in heritably vulnerable individuals upon exposure to environmental risk factors. IBD basically affect young adult populations, altering their quality of life and rising morbidity, matched to the general population **(Maaser et al., 2019).** The prevalence of IBD has risen ultimately in countless regions of the world, creating a extensive social and economic burden on health systems. In 2017, 6.8 million IBD cases were recorded globally. In Egypt, a little epidemiological data regarding IBD are available; conversely, some studies indicate the comparative incidence ratio of UC and CD is 6:1**(Lang-Schwarz et al., 2021)**

The triggers and pathogenesis of IBD are nonetheless difficult to understand. The pathogenesis of IBD involves genetic factors and environmental factors **(van der Sloot et al., 2017).** Dairy products could be accused in the enhancement of IBD by modifying influences on intestinal microbiota and immune reactions. Where dairy nutrients are contrarywise associated with low-grade inflammation and influence key cytokines such as tumor necrosis factor alpha in the pathogenesis of IBD. Moreover, patients' habits such as smoking, dietary fiber (especially vegetables and fruits), saturated fats, sleep disturbances, depression, and reduced vitamin D levels have been accompanied by elevated IBD incidence. As well as , stress, microbiota, some medications, NSAIDs and early antibiotic exposure during infancy are factors that may raise the chance of developing IBD, especially in genetically sensitive people. **(Nieman et al., 2021).**

Inflammatory bowel disease is presented by diarrhea, rectal bleeding, and abdominal ache gas/bloating, bowel incontinence, fever, and weight loss **(Zeitz et al., 2016).** Also, extraintestinal symptoms (EIMs) can happen in a few patients and may affect joints, the hepatobiliary system, skin, eyes and fatigue may be also observed **(Shantanam &**

MUELLER, 2018). The disease process is linked to bone loss that make patients are liable to osteoporosis not only because of chronic inflammation but also related to repeated usage of corticosteroids, which stimulates osteoclastogenesis **(Lima, 2015).** An important complication of IBD is the malignant transformation of colonic mucosa that increases the incidence of colorectal carcinoma. Diagnosis of IBD should be depend on both history taking, and physical examination which is accomplished by reviewing laboratory results (i.e., blood and fecal inflammatory markers), afterwards endoscopic evaluation of diagnostic imaging through esophagogastroduodenoscopy or ileocolonoscopy, and the pathological analysis of multiple taken biopsies **(Gajendran et al., 2019).**

Medical treatment of IBD is customized. The selection of medication and its rout of administration (oral, rectal, injection, and infusion) depending on a variety of elements, such as type, site, and severity level of the disease, in addition to other historical and biochemical prognostic factors, and patient partialities. Conventionally, relining on the severity level, IBD may demand immunosuppression to control symptoms, and anti-inflammatory steroids for adjusting disease flares. While severe cases may require surgery, for instance temporary or permanent colostomy or ileostomy. A quite new treatment alternative in form of fecal bacteriotherapy and fecal microbiota transplantation, which have been effectively used in a limited situations **(Putignani et al., 2016).**

Both IBD types have a massive effect on patients' survival and appear with plenty of unknowns. Nurses should offer IBD patients with an extreme deal of reinforcement, guidance, comradeship, care, and empathy **(Rosso et al., 2021).** Also, nurses should be cautious of these patients who can struggle with the harmful health impacts of the disease at separate times. Where worry, anxiety, and their physical state will thwart their capacity to understand information, which must be discussed in a way that is not easily unrecognized. So IBD caring nurses can give patients sound counsel and practical direction about important patient concerns, such as diet, social issues, usual IBD warning signs and complications, IBD causes, drugs and possible haunted side effects, and surgical procedures. Likewise, provide emotional sustenance to patients by supporting them to express their worries in order to improve their daily life burden. So, the fundamental nursing role for patients with IBD concentrates on educating the patient with basic information about diagnostic and therapeutic regimens and performing an assessment regarding the impact of IBD on patients' daily life burden including physical, psychological, social, and psychological aspects. **(Ruan et al., 2020).**

Significance of the study:

Inflammatory bowel disease patients with persistent chronic relapsing and remitting disease courses are growingly incurring a lot of costs associated with healthcare utilization, financial expenditures, and work productivity casualties, necessitating a pressing need for cost-effective care strategies to address these burdens on IBD patients and their families (Park et al., 2020). From this regards a well-formulated protocol of nursing care is essential to be a comprehensive tool that helps each patient to understand IBD conditions, treatments, medications side effects, or risks that may occur to a specific patient based on unique circumstances. Therefore, a protocol of nursing care is important in meeting the patient's needs and improving patients' quality of life and decreasing their daily life burden related disabilities **(Mancina et al., 2020).**

Aim of the study:

This study aimed to evaluate the effect of implementing a protocol of nursing care on daily life burden of patients with inflammatory bowel diseases.

Operational definition of protocol of nursing care: means instructional program that include complete overview about IBD and its nursing management instructional guide.

Research hypothesis: To follow the aims of the study, the subsequent research hypothesis was made:

Studied patients receiving a protocol of nursing care regarding inflammatory bowel diseases management exhibit lower daily life burden than those who didn't receive it.

Materials and Method

Research design: a quasi-experimental research design was consumed in the present study.

Setting: The present study was carried out in Outpatient Rheumatology Clinic (the clinic has surrounding waiting area and receives patients Monday weekly from 9 am- 12 pm) at Damanhour National Medical Institute in Elbehira governorate, Egypt.

Subjects: A purposive sample of 70 adult patients admitted to the above-mentioned study setting, were divided randomly into two identical groups; a study group, consisting of 35 adult patients who received the protocol of nursing care, and a control group, consisting of 35adult patients who received routine hospital care only. The patients who contributed to this study, were selected corresponding to the following criteria.

- Adult patients of both sexes aged from 20 ≤ 60 years.

- Had mild or moderate UC or CD at the time of interviews

- Free from comorbid disease as cancer colon.

Tools

Two tools were used to perform the study: -

Tool I: The Inflammatory Bowel Disease Patient's Socio Demographic &Clinical Data Assessment Schedule: It was established by researchers based on various international and national literature**(Daperno et al., 2017; Lang-Schwarz et al., 2021; Moreau et al., 2021)** which contained 2 parts:

Part I: patients' sociodemographic such as age, sex, marital status, educational level, occupation, area of patient's residence.

Part II: patient's clinical data: This part comprises items related to type of inflammatory bowel disease, associated diseases, duration of illness, treatment, history of smoking, patients' BMI, changes in activities of daily living, frequently consuming diet, and number of hospitalizations related to IBD complication.

Tool II: The Inflammatory Bowel Disease Disk (IBDD)

This tool was structured by **Ghosh et al. (2017).** It is self - reported scale used for assessing the IBD-its associated limitations component regarding the past week including ten items: joint pain, abdominal pain, body image, education and work, emotions, energy, interpersonal interactions, regulation of defecation, sexual function, and sleep. An IBD-disk tool encompasses a questionnaire with an illustrative statement for all items which scored on disc-shaped visual analogue scale from 0–10 [0 = absolutely disagree; 5 = neither agree nor disagree; 10 = absolutely agree or maximal disability]. The overall IBD-disk score was calculated as the summation of its 10 components, ranging from 0 to 100. Burden scale has been used to study the burden of IBD, and the total score was categorized as follow:(Ghosh et al., 2017)

- Low burden < 50%
- Moderate burden 50 < 75%
- High burden 75- 100%

Method

- Permission to collect data for the study was taken from the directors of the previously mentioned study setting after an explanation of the study's purpose.

- Tool I was developed by the researcher based on the recent related literature review while tool II was adopted from **Ghosh et al.,2017.**

- Validity: The tools were examined for face and content validity by (7) specialists ; (2 experts from medical-surgical nursing, Faculty of Nursing, Alexandria University; 2 specialists from Medical-Surgical Nursing, Faculty of Nursing, Damanhour University and in addition to three experts in the gastrointestinal field. Minimal adjustments were made to assemble the jury's opinion.

- Reliability test was accompanied by using Cronbach's Alpha which was 0.78

- Pilot Study: A pilot study was performed before initial data collection on 10% of the study patients (both groups) to appraise the tentatively settled tools for precision and pertinency and to estimate the time required to collect data then needed modifications were performed out before the real study. Data acquired from the pilot study was omitted from the current study.

Data collection:

- Data were gathered throughout the period from 1/4/2022 to 5/10/2022. At the primary interview, the researcher presented herself to begin a line of interaction to facilitate the implementation of the tools. The researcher randomly distributed the patients into both the control group and the study group and an interview with every patient individually illuminated the aim of the study.

- The control group who would receive routine hospital care (in the form of outpatient follow-up visits and disbursement of the prescribed treatment at the expense of the state) was interviewed and evaluated by using (tool I and tool II). Tool (I) was used to collect the demographic and clinical characteristics. Also, tool II was used for each patient individually to assess each component of the IBD-related incapacity during the past week. Moreover the time needed for completing the study tools for each patient ranged from 15- 30 minutes pre protocol, post 2 weeks, and post 4 weeks of follow up.

- For the study group patients who would subjected to a protocol of nursing care was interviewed and assessed by using (tool 1 and tool II). Tool (I) was used to collect the demographic and clinical characteristics. Also, tool (II) was used for each patient individually to assess each component of the IBD-related disability during the past week. Moreover; the time needed for completing the study tools for each patient ranged from 15- 30 minutes (pre implementation of the protocol of nursing care, post 2 weeks, and post 4 weeks after protocol implementation).

- **The protocol of nursing care was conducted in three phases as follows:**

I-Preparatory phase: the development of a colored booklet constructed on related literature **(Daperno et al., 2017; Kaplan et al., 2019; Shale & Hospital, 2003)** It included colored illustrated pictures of Ulcerative colitis and Crohn's disease overview, causes, symptoms, methods of diagnosis, surgical intervention, treatment for mild, moderate, and severe symptoms. In addition to instructional guide regarding recommended diet, smoking hazards, medications and exercise compliance, commitment with follow up appointments, Importance of psychological and social support and safety of pregnancy with IBD, and complication of IBD.

II-Implementation phase: in which patients of the control group (1) had routine hospital care. – whereas;

patients of the study group (2) had the protocol of nursing care by the researchers and was executed into **2 sessions** while using the educational booklet:

- **The first session that was conducted at the first individualized interview for each patient, lasting 30-45 minutes and divided into two main parts:**

Part one: Informational overview about ulcerative colitis and Crohn's disease overview, causes, symptoms, methods of diagnosis, surgical intervention, treatment for mild, moderate, and severe symptoms and complication of IBD.

Part two: IBD nursing management instructional guides regarding recommended diet, smoking hazards, medications and exercise compliance, commitment with follow up appointments, Importance of psychological, social support and safety of pregnancy with IBD.

- **The second session was performed by the researchers for the study group after 2 weeks to reinforce the given information at the previous session using illustrated educational booklet.**

III- The evaluation phase: This phase was implemented after the second and fourth weeks from the implementation of a protocol of care in previously mentioned settings emphasizing estimating the effect of implementing a protocol of nursing care on daily life burden of patients with inflammatory bowel diseases using tool 2 (post- test), for both groups.

Ethical Considerations:

The research approval was gotten from the ethical committee in the faculty of nursing, Damanhour University before initiating the study. Official approval was taken from the administrator of the study setting. An informed written consent from patients to apply for this study was secured. Patients were also informed that participation was voluntary, and they had the right to withdraw at any time without granting a reason. The researcher was ensured of maintaining anonymity and confidentiality of the objective data. The privacy of study subjects was counted during data collection. Furthermore, the patients were informed that this data would not be reused in another research without their approval.

Statistical analysis:

Data was collected then tabulated and statistically analyzed using Statistical Package for Social Sciences (SPSS) version 25. Data expressed as number, percentage, mean and stander deviation were used to describe the basic data. Chi-square test was used for categorical variables to compare between different groups. Pearson's correlation coefficient was used to measure the statistical relationship, or association, between two continuous variables. Values of p were involved as the significance levels for testing the research hypotheses.

Results:

Table (1) showed that (45.7% and 42.9% respectively) of the control and study groups were between the ages of 20 and 30 years while (65.7% and 71.4% respectively) of them were female. Regarding education (48.6%) of the control group and (57.1%) of the study had secondary education. Concerning occupation, (34.3% and 37.1 %respectively) of the control and study groups have manual work. Also, (57.1 and 51.4% respectively) of the control and study groups were married. Regarding the place of residence (62.9%) of the control group were from urban areas while (51.4%) of the study group were from rural areas. No statistical significance differences were found between the control and study groups with their socio-demographic characteristics.

Table (2) illustrated that (54.3% and 51.3% respectively) of the control and study groups had BMI values of less than 18.5 kg/m2 (underweight), and (71.4% and 77.1% respectively) of the control and study groups had ulcerative colitis. While (48.6%) of the control group and (34.3%) of the study group had hypercholesterolemia. Also, (57.1% and 60.0% respectively) had a duration of IBD illness between 1– 3 years.

Regarding the changes in activities of daily living, (42.9 % and 40.0% respectively) of the control and study group had changes in eating, while (20.0% and 22.9% respectively) of the control and study group had changes in elimination pattern. In addition, (48.6% and 42.9% respectively) of the control and study groups were frequently consuming chicken. No statistically significant differences were found between the two groups in relation to their clinical data.

Table (3) Clarified that the Mean ±SD of control group post 4 weeks of implementation of the protocol of care related (abdominal pain, regulation of defecation, interpersonal interactions, education and work, sleep, energy, emotions, body image, sexual function, and joint pain) were (8.91±0.445, 9.29±0.622, 7.20±0.759, 8.97±0.618, 7.77±0.690, 8.86±0.692, 8.74±0.852, 6.66±0.765, 5.69±1.90, 8.91±0.445 respectively). Compared to the Mean ±SD of the study group post 4 weeks from the implementation of protocol of care that were (5.69±0.67, 4.31±0.71, 5.31±0.68, 5.31±0.718, 4.86±0.69, 5.63±0.877, 6.06±.1.53, 5.06±0.76, 3.06±0.76, and 5.69±.676 respectively), which indicated low burden of irritable bowel syndrome.

Table (4) Concerning the study group; it was observed that, there was a highly statistically significant difference between pre and post-2 weeks of implementation of protocol of care, as well as pre and post-4 weeks of implementation where p-value=0.000** for both. Furthermore, there was a statistically significant difference post 2 and 4 weeks of implementation of the protocol of care where p-value = 0.031*.

Table (5) showed that there was a significant positive correlation between study group patients' irritable bowel syndrome burden scores pre-the protocol of care and their educational level where p-value=0.011*, while there was a significant positive correlation between study group patients' irritable bowel syndrome burden scores post-4 weeks of implementation of the protocol of care and their occupation where p-value=0.031*. Compared to the control group, it was noticed that there was no significant correlation found pre, and post-4 weeks of routine care. On the other hand, there was no significant correlation found between both studied groups and their clinical data pre and post 4 weeks of care.

Table (1): Distribution of the studied patients according to their socio-demographic characteristics.

Demographic Characteristics	Control group (N=35)		Study group (N=35)		Total (N=70)		X^2 P
	No	%	No	%	No	%	
Age							
• 20<30	16	45.7	15	42.9	31	44.3	
• 30<40	16	45.7	11	31.4	27	38.6	X^2=3.958
• 40≤50	3	8.6	9	25.7	12	17.1	P=0.138
Gender							
• Male	12	34.3	10	28.6	22	31.4	X^2=0.000
• Female	23	65.7	25	71.4	48	68.6	P=1.000
Educational qualification							
• Primary education	4	11.4	4	11.4	8	11.4	X^2=0.603
• Secondary education	17	48.6	20	57.1	37	52.9	P=0.740
• University	14	40.0	11	31.4	25	35.7	
Occupation							
• House wife	9	25.7	12	34.3	21	30.0	X^2=1.467
• Manual	12	34.3	13	37.1	25	35.7	P=0.480
• Not work	14	40.0	10	28.6	24	34.3	
Marital status							
• Single	11	31.4	12	34.3	23	32.9	
• Married	20	57.1	18	51.4	38	54.3	X^2=1.349
• Widow	1	2.9	3	8.6	4	5.7	P=0.718
• Divorced	3	8.6	2	5.7	5	7.1	
Place of residence							
• Rural	13	37.1	18	51.4	31	44.3	X^2=1.447
• Urban	22	62.9	17	48.6	39	55.7	P=0.168

***Significant at p <0.05** **X: Chi square**

Table (2): Distribution of the studied patients according to their clinical data.

Clinical data	Control group (N=35)		Study group (N=35)		Total (N=70)		X^2 P
	No	%	No	%	No	%	
BMI kg/m2							
• Underweight	19	54.3	18	51.3	37	52.9	
• Healthy	14	40.0	16	45.7	30	42.8	X^2=0.368
• Overweight	2	5.7	1	2.9	3	4.3	P=0.832
Type of inflammatory bowel disease							
• Crohn's disease	10	28.6	8	22.9	18	25.7	X^2=0.299
• Ulcerative colitis	25	71.4	27	77.1	52	74.3	P=0.393
Associated diseases							
• Hypercholesterolemia	17	48.6	12	34.3	29	41.4	
• Diabetes mellitus	9	25.7	8	22.9	17	24.3	X^2=2.699
• Hypertension	5	14.3	10	28.6	15	21.4	P=0.440
• Chronic obstructive pulmonary diseases	4	11.4	5	14.3	8	11.4	
Duration of illness							
• Less than 1 year	8	22.9	8	22.9	16	22.9	
• 1– 3 years	20	57.1	21	60.0	41	58.6	X^2=0.101
• >3 years	7	20.0	6	17.1	13	18.6	P=0.951
Number of hospitalization for respiratory problem							
• Nil	24	68.6	12	34.3	36	51.4	
• 1 – 3 times	10	28.6	22	62.8	32	45.7	X^2=1.203
• 3 – 6 times	1	2.9	1	2.9	2	2.9	P=0.548
History of smoking							
• Do not smoke	14	40.0	17	48.6	31	44.3	
• < 1 packet/day	9	25.7	6	17.1	15	21.4	X^2=0.687
• 2-3 packets/day	5	14.3	4	11.4	9	12.9	P=0.876
• >3 packets/day	7	20	8	22.9	15	21.4	
Changes in activities of daily living							
• Bathing	3	8.6	2	5.7	5	7.1	
• Elimination and using toilets	7	20.0	8	22.9	15	21.4	
• Walking	3	8.6	4	11.4	7	10.0	X^2=0.444
• Eating	15	42.9	14	40.0	29	41.4	P=0.979
• Getting in and out of bed and chair	7	20.0	7	20.0	14	20.0	
Frequently consuming diet							
• Chicken	17	48.6	15	42.9	30	42.9	
• Meat	6	17.1	8	22.9	16	22.9	X^2=1.200
• Sea food	11	31.4	9	25.7	20	28.6	P=0.753
• vegetarian	1	2.9	3	8.6	4	5.7	

***Significant at p <0.05** **X: Chi square**

Table (3): Mean and standard deviation of the studied patients according to their inflammatory bowel disease- related disability pre and post the protocol of care.

The Inflammatory bowel disease related disability		Control group			Study group		
		Pre protocol	Post 2 weeks	Post 4 weeks	Pre protocol	Post 2 weeks	Post 4 weeks
1. Abdominal pain	Mean ±SD	9.09±0.658	8.71±.519	8.91±0.445	9.26±0.657	3.69±0.67	5.69±0.67
	Min-Max	8-10	8-10	8-10	8-10	3-7	5-7
2. Regulation of defecation	Mean ±SD	9.17±0.717	9.17±.568	9.29±0.622	9.43±0.608	6.77±0.94	4.31±0.71
	Min-Max	8-10	8-10	8-10	8-10	5-8	4-7
3. Interpersonal interactions	Mean ±SD	7.17±0.785	7.26±.780	7.20±0.759	7.51±0.781	5.89±0.67	5.31±0.68
	Min-Max	6-8	6-8	6-8	6-9	5-7	4-7
4. Education and work	Mean ±SD	9.03±0.664	9.14±.601	8.97±0.618	9.09±0.612	5.91±0.74	5.31±0.718
	Min-Max	8-10	8-10	8-10	8-10	5-7	4-6
5. Sleep	Mean ±SD	7.66±0.765	7.69±.718	7.77±0.690	8.00±0.907	3.38±0.724	4.86±0.69
	Min-Max	7-10	7-9	7-9	7-10	3-6	4-7
6. Energy	Mean ±SD	8.77±0.770	8.86±.692	8.86±0.692	8.97±0.707	5.69±.676	5.63±0.877
	Min-Max	7-10	8-10	7-10	8-10	5-7	4-7
7. Emotions	Mean ±SD	8.71±893	8.86±.810	8.74±0.852	9.06±0.725	5.86±0.69	6.06±.1.53
	Min-Max	7-10	7-10	7-10	8-10	4-7	4-8
8. Body image	Mean ±SD	6.69±0.796	6.63±.808	6.66±0.765	6.40±0.55	5.86±1.417	5.06±0.76
	Min-Max	5-8	5-8	5-8	6-8	4-8	4-7
9. Sexual function	Mean ±SD	5.77±2.016	5.80±2.055	5.69±1.90	6.23±1.73	3.31±0.718	3.06±0.76
	Min-Max	4-9	4-9	4-9	4-9	3-6	3-7
10. Joint pain	Mean ±SD	9.09±0.658	8.71±.519	8.91±0.445	9.26±0.65	6.63±.808	5.69±.676
	Min-Max	9-10	8-10	8-10	8-10	5-8	5-7

Table (4): Distribution of the studied patients according to their levels of daily life burden related disability throughout intervention periods of the study.

The burden of irritable bowel syndrome	Study group (n=35)						Test of Sig	Control group (n=35)						Test of Sig
	Pre Protocol of care		Post 2 weeks		Post 4 weeks		p-value	Pre Protocol of care		Post 2 weeks		Post 4 weeks		p-value
	No	%	No	%	No	%		No	%	No	%	No	%	
• High burden	29	82.9	7	20.0	6	17.1	X= 49.60 P= 0.000*	24	68.6	23	65.7	25	71.4	X= 0.370 P= 0.984
• Moderate burden	4	11.4	22	62.9	13	37.1		8	22.9	8	22.9	7	20.0	
• Low burden	2	5.7	6	17.1	16	45.7		3	8.6	4	11.4	3	8.6	
Pre protocol, Post 2weeks	X= 27.906 P= 0.000**							X= 0.1641 P= .921						
Post 2 weeks, post 4 weeks	X= 6.936 P= 0.031*							X= 0.292 P= 0.863						
Pre protocol, Post 4 weeks	X= 30.767 P= 0.000**							X= 0.087 P= 0.957						

*Significant at p <0.05 **High significant at p <0.001 X: Chi square

Table (5): Correlation between socio-demographic characteristics and clinical data of the studied patients with their burden of irritable bowel syndrome scores pre and post 4 weeks of protocol of care.

Demographic Characteristics	The burden of irritable bowel syndrome scores							
	Study group (n=35)				Control group (n=35)			
	Pre protocol of care		Post 4 weeks		Pre protocol of care		Post 4 weeks	
	Pearson's r	P-value	Pearson's r	P-value	Pearson's r	P-value	Pearson's r	P-value
• Age	0.086	0.625	-0.016	0.928	0.073	0.675	-0.187	0.282
• Sex	0.140	0.421	0.182	0.297	0.055	0.752	0.113	0.520
• Education	0.426	0.011*	0.205	0.236	-0.187	0.283	-0.229	0.186
• Occupation	-0.180	0.301	0.364	0.031*	0.138	0.428	0.011	0.949
• Marital status	0.135	0.440	0.107	0.540	0.069	0.692	0.056	0.750
• Place of residence	0.223	0.199	0.101	0.562	0.030	0.862	0.071	0.684
Clinical data								
• BMI kg/m2	-0.298	0.082	-0.140	0.422	-0.235	0.174	-0.016	0.927
• Type of inflammatory bowel disease	-0.105	0.550	-0.004	0.982	-0.227	0.189	-0.127	0.466
• Associated diseases	-0.058	0.741	0.002	0.993	-0.092	0.600	0.008	0.466
• Duration of illness	0.214	0.217	-0118	0.500	0.251	0.147	0.156	0.372
• Number of hospitalization for respiratory problem	0.083	0.636	-0.057	0.745	-0.157	0.366	-0.019	0.915
• History of smoking	-0.016	0.927	0.071	0.686	-0.058	0.741	0.123	0.483
• Activities of daily living	0.048	0.786	0.080	0.649	-0.065	0.709	-0.080	0.648
• Frequently consuming diet	0.052	0.766	0.058	0.739	-0.048	0.785	0.044	0.802

Interpretation of r: Weak (0.1-0.24); Intermediate (0.25-0.7); Strong (0.75-0.99)
***Significant at p <0.05**

Discussion

Inflammatory bowel diseases [IBDs] are chronic inflammatory disorders that adversely pretend to various aspects of patients' daily life. Hence new guidelines of care, taking into account IBD-related incapacity and daily-life burden, which are progressively being taken into account in clinical practice. **(Tadbiri et al., 2021),** for this regards a well formulated a protocol of nursing care is curial in refining patients quality of life and decreasing daily life burden ,because nurses have a vital role in safeguarding patients adherence to the standards and to stipulate effective and safe patient care, so the aim of this study is to evaluate the effect of implementing a protocol of nursing care on daily life burden of patients with inflammatory bowel diseases.

In relation to patients' sociodemographic *data*, the findings of the present study demonstrated that, less than half of the control and study groups were between the ages of 20 and 30 years This finding was supported by **Kaplan et al.,2019** who studied The Impact of Inflammatory Bowel Disease in Canada and found that age groups that are furthermost probable to be diagnosed with Crohn's disease and ulcerative colitis are adolescents and those between the

ages of 20 to 30 that may ascribed to dietary pattern in this age group , with a higher consumption of fats and refined sugars and condensed consumption of dietary fiber , overpoweringly changes the gut's microbiome. On other hand **Singh et al., 2014** reported that the patients between 50 and 60 years were frequently exaggerated by Inflammatory bowel diseases more than other age groups in relation to degenerative mucosal changes. (Singh et al., 2014). Furthermore, **Lamers et al., 2021** they reported that the usual age group affected was between 40- 60 years. (Lamers et al., 2021). On contrary, **Rosen 2016**, accentuated that young children are at particularly high risk for Inflammatory bowel diseases due to their miserable level of immunity **(Rosen et al., 2016).**

The present study showed that, nearly two third of the control and study groups were female. This could be interpreted as females have greater risk to develop IBD than males as females at higher risk for environmental changes that amend the gut microbiome, that thought to be an important trigger of the disease. Therefore, exposures like altering by breastfeeding patterns, hormone exposure during childhood, puberty, and menopause/andropause and, dietary changes throughout life might play a role in IBD pathogenesis and disease course. This result comes in line with (**Kaplan et al.,2019)** study findings which verified that, Women compromised a majority of the study group, and he rationalized that, females had lifestyles as the use of the over counter medications such as analgesics and antibiotics. On the contrary **(Mitchell et al., 2019),** did descriptive study about concerns of IBD patients, assumed that the incidence of IBD among males was greater than females. He suggested that these results may be due to an raised percentage of smoking aggravating IBD.

Regarding level of education, nearly half of the control and study groups were had a secondary education, this come in line with **Cosnes** , He found that the majority of patients having a secondary education that related to disease burden .**(Cosnes et al., 2012)** And also , it was found that less than two-thirds of the control group were from urban areas while around half of the study group were from rural areas. **Peña-sánchez (Peña-sánchez et al., 2023)**

The study results illustrated that around half of the control and study groups had *BMI* values of less than 18.5 kg/m2 (underweight). On the other hand **Profile et al., 2017** illustrated that regarding body mass index (BMI), results showed that 69.80% of participants, revealed normal BMIs. That may be attributed to patients having diarrhea during an active symptom flare, and decreased appetite can lead to weight loss. With chronic inflammation. An increased demand for protein is often the result of chronic inflammation. When this happens, patients' body may start to break down muscle and other fat-free areas of mass. The decrease in muscle mass can cause weight loss.

Concerning to type of *inflammatory bowel disease* it was observed that more than two-thirds of both the control and study groups had ulcerative colitis. similar finding was obtained by **Moreau C** who found that ulcerative colitis (UC) associated with high somatic symptom burden, reduced quality of life, and increased psychological distress.**(Moreau et al., 2021).** On contrary **Tadbiri** found that y more than two third of the patients had Crohn's disease **(Tadbiri et al., 2021).** As regards associated diseases, more than one third of both groups had hypercholesterolemia, this results come in line with Emran who found that study patients had hypercholesterolemia with gastrointestinal infections **(Emran et al., 2022).** On contrary **Sands** found that patients with IBD show lower levels of total cholesterol, HDL-c and LDL-c, as compared to the general population, "This observation is more clearly seen in patients with active IB disease"**(Sands et al., 2021)** also, **Opstelten** found that patients with active ulcerative colitis may lose weight from limiting their food intake due to their bowel symptoms, and this may in turn lead to lower cholesterol levels,"**(Opstelten et al., 2016)**

Regarding the *history of smoking*, more than quarter of the control group smoked < 1 packet/day and near than quarter of the study group smoked >3 packets/day. This come in line with **Álvarez** who found that CD patients who smoke complain of a worse prognosis of illness and quality of life, and are more liable to encounter complications, have multiple hospitalization, show a crueler response to treatments, and have a bigger need for surgery**(Álvarez-lobos, 2018).** Also **Opstelten** who found that smoking has well-established harmful effects on CD, gut microbial gene richness, and species diversity were diminished in smokers **(Opstelten et al., 2016)** .Concerning *changes in activities of daily living* it was noted that more than quarter of the control and study group had variations in eating, while more than one-fifth of the control and study group had changes in elimination pattern. This results supported by **Range**, who found that eating pattern changes are complex psychological circumstances exemplified by instability in eating and changes in elimination pattern.

In relation to inflammatory bowel disease-related disability pre and post- implementation of the protocol of care , the current results showed that, there was a noteworthy statistical significant difference between mean scores and standard deviation of inflammatory bowel disease-related disability pre and post- implementation of the protocol of care related (abdominal pain, regulation of defecation, interpersonal interactions, education and work, sleep, energy, emotions, body image, sexual function, and joint pain) between the control and study groups which shown low burden of irritable bowel syndrome in study group after implementation of the protocol of nursing care . This might be defended by claiming that providing patients with health education helps them better understand their conditions, enhance their use of self-care, and boost their satisfaction of nurses' service. That result came in line

with(Lackner et al., 2018), who found that, patient satisfaction with the provided nursing care may have been intensified as they were treated absolutely within clinical practice. Also, **Mitchell** recognized that, efficiently knowledgeable patients with IBD are more probably to adjust to their condition and upgrade their quality of life than non-informed patients**(Mitchell et al., 2019)**

Furthermore, there was a statistically significant difference post 2 and 4 weeks of implementation of the protocol of care, this may be related to that formal IBD patient education program which improve patients perceived knowledge and patients' satisfaction and provide them with positive trends toward greater medication obedience and minor health care use. This finding was supported by **Huerta,** who illustrated that negative outcomes often were due to lack of training and direction from one who is responsible of nursing services. Moreover, nursing guiding is a moderating influence that affecting the patients' safety. Also, Enhancement in nurses' knowledge and clinical skills concerning caring for IBD patients after achieving training. Moreover the implementation of the educational training program has amended patients' care and facilitated a healthier working environment for staff, as well as, fast improvements were accomplished in IBD patients' competencies, so well patient knowledge of the disease, its principles of management and treatment, could expand disease outcomes and decline impact on daily life burden. **(Huerta et al., 2019)**

The present study results showed that there was a significant positive correlation between study group patients' irritable bowel syndrome burden scores pre-the protocol of care and their educational level, this come in line with Gottfried **Novacek M.D 2019** who found that the disease prognosis was associated with greater age at diagnosis and a higher educational level. So Proper cooperation between nurse and patient, that improve patient's awareness of the core of the disease, and recommendations for lifestyle reformation, dietary alteration, and physical activity are generally dependent on educational level.

The present study results discovered that there was a meaningful positive correlation between study group patients' irritable bowel syndrome burden scores post-4 weeks of implementation of the protocol of care and their occupation. This result supported by **Profile** who found that IBS patients reported having jobs displaying a decreased economic status, 47.90% a medium without educational intervention **(Profile et al., 2017)** . As well **Huerta** identify that Irritable bowel syndrome (IBS) is a stress-related disease associated with psychosocial influences, while knowledge about its occupational psychosocial features is threatened. That could be justified that patients who understand the profits and hazards of a disease management plan are expected to be more tolerant of it and willing to pledge in and follow their treatment and monitoring programs**(Huerta et al., 2019).**

Conclusion and recommendations

It can be concluded that protocol of nursing care of patients with inflammatory bowel diseases had a crucial role in adjusting patients' compliance with therapeutic regimen which positively influences their daily life burden related disabilities.

Built on the results of the current study, the following recommendations are proposed.

- Pre-service training instructions should be supplied to the newly assigned nurses before undertaking autonomous responsibilities for IBD patients' care.

- Established competencies fliers about care for IBD patients would be accessible to all staff nurses in medical departments and outpatient clinics.

- Further studies need to be conducted to evaluate the incidence, prevalence of IBD and its effect on patients' psychosocial life in Egypt.

Study Limitations:

- The most important limitation of this study was that the setting (the Outpatient Rheumatology Clinic) surrounding waiting area was very crowded area and no specialized room for patient education .

Conflict of interest :

The authors confirm that the publication of this paper does not involve any conflict of interest.

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