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Original Article

Outcomes of a Structured Program for Bowel Preparation in Patients Scheduled to Undergo Colonoscopy: A Randomized Controlled Trial

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Abstract ***Objectives:*** **An important element that affects the diagnosis and procedure ofcolonoscopy is the cleanliness of the bowel preparation.**

Methods: **This study was to investigate the incidence of repeated endoscopy. The intestinal preparation is not clean, and to assess knowledge and practice in patients receiving colonoscopy compares between the two groups. Randomized controlled trial of 63 control subjects. Get regular care. The experimental group received 67 structured bowel preparation programs. The instrument used to collect data was a questionnaire using standard deviation, chi-square, independent *T*-test, relative risk.**

Results: **The results showed that repeated endoscopy was not found in the two groups. However, in the experimental group, colorectal intestinal disease was fair level 0.81 times that of the control group ($p = 0.1540$), which is approximately a 13% difference. With regard to subjects' understanding before and after giving knowledge, both groups had a similar percentage of correct responses at 80%. Regarding the suitable diets for the first and second day, the correct response rate differed with 5% correct in the pre-test and 1.9% correct in the post-test. On the topic of drinking water following defecation, there was a statistically significant difference where the results of the group that drank water ($p < 0.05$) was 13.5 times that of the group that did not ($p = 0.02$).**

Conclusions: **Although the results were not statistically significant, the experimental group that received a structured bowel preparation program had a tendency to have a very good level of cleanliness, higher than that of the control group. Patients should also self-assess their intestinal cleanliness. It is recommended that this be studied further in these subgroups.**

Keywords: **Enhancement program, bowel preparation, colonoscopy**

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Introduction

An important factor that affects the effectiveness of colonoscopy and a clinician's ability to diagnose abnormality is the cleanliness of the patient's bowel. Inappropriate bowel preparation may hide or obscure signs of disease and the presence of tumors. Examination of the cecum may be difficult (or impossible), which increases the risk of complications, such as diverticular diseases, infection, and gas. Patients who undergo a failed colonoscopy have to endure a repeat procedure. Data from the Siriraj Hospital GI Endoscopy Center from 2011 (B.E. 2554)[1] revealed that 28% of patients had to undergo repeat colonoscopy, which resulted in increased risk of complications (e.g., flatulence), and increased operative time to perform the procedure, because repeat patients have to receive a higher dose of anesthesia. Moreover, increased expense was incurred by both patients and the hospital.

Our review of the literature relative to bowel preparation for colonoscopy revealed two approaches to bowel preparation - split dose regimen and same day regimen[2,3,4]. Both approaches have advantages and disadvantages. Split-dose regimen requires patients to take laxatives on both the day before and on the day of the procedure. The same day regimen requires patients to take a laxative in the morning for a colonoscopy that is scheduled for the afternoon. Both approaches have studies that support their efficacy. Moreover, two different bowel preparation strategies allow for more choice relative to patient convenience and preference. Increased patient awareness regarding the importance of bowel preparation will increase the rate of successful colonoscopy, improve the detection of present tumor or other abnormalities, and decrease the rate of repeat colonoscopy.

This study therefore developed a structured bowel preparation program by adapting the split dose regimen to fit into the organizational culture. This program consisted of providing advice, a bowel preparation manual, telephone calls, and monitoring preparation for the colonoscopy. The population was separated into two groups: a group that received the structured bowel preparation program, and a group that received regular care. The researchers hypothesized that the group that underwent the program would result in high levels of cleanliness or higher than that of the statistics collected by the Siriraj Gastrointestinal Endoscopy Center. Expected benefits of the research are to help reduce repeated colonoscopies.

Research Objectives

The primary objective is to study the incidence of repeated colonoscopies from unclean bowel preparation by comparing the control group and experimental group. The secondary objectives are to assess the knowledge and practice of colonoscopy patients between the aforementioned two groups, and to find other causes of unclean bowel preparation.

Hypothesis

A structured bowel preparation program for patients scheduled to undergo colonoscopy will help to reduce the incidence of repeat colonoscopy.

Materials and Methods

This study is experimental procedure/intervention using a structured bowel preparation program, which has minimal risk. The allocation of the study population is through randomized controlled trial by using a computer program to randomly sequence relevant documents into sealed opaque envelopes. After explaining the study to the patients, they selected an opaque envelope in the order given by the computer program to see if they were in the control or experimental group.

Population and Samples

The population consisted of Siriraj Hospital GI Endoscopy Center colonoscopy patients aged 18-75 years. The method of recruitment of the study population was from patients who had appointments at the center. Patients who met the research participation qualifications were given information by the researchers and gave their consent to participate. The duration of data collection was from November 2015 (B.E. 2558) to March 2017 (B.E. 2560). The inclusion criteria were: patients who came for their first colonoscopy aged 18-75 years, are able to take care of themselves, and can communicate and understand Thai. The exclusion criteria were: patients with gastrointestinal bleeding, emergency patients, patients with chronic renal failure, patients who are unable to take care of themselves, and patients who did not want to participate.

Data Collection

The research process was as follows: Recruitment of the study population was undertaken through a randomized controlled trial from a computer program's random sequencing in sealed opaque envelopes. After explaining the study details to patients, they selected an envelope to determine which of the two groups they would be part of, namely, 1) the control group which received advice and guidance documents from nurses on bowel preparation using the regular approach, a guidance for colonoscopy patients, and undertook a pre-test and post-test after receiving information, as well as evaluation; and 2) the experimental group, which received advice and guidance documents from nurses using the new approach, with advice from nurses on how to prepare bowels using flip charts, and undertook a pre-test and post-test after receiving information, as well as received further information on their areas of inquiry, evaluation, and telephone calls to remind patients to prepare two days before their colonoscopy and give them more information on the study.

If patients consented to participating in the study, the researcher asked them to sign their consent and select a sealed brown envelope to be put into their group. The study participant would then be given advice and guidance documents from nurses specific to their group, be evaluated by the practitioner who performed the colonoscopy on the cleanliness, and be determined on whether a repeat colonoscopy is necessary and for what reason.

Assessment of Research Tools

The research tools were questionnaires and evaluation forms with content inspection by three experts.

This study received approval from the Siriraj Institutional Review Board of the Faculty of Medicine Siriraj Hospital (Project Code: 501/2558(EC3)).

Data Analysis

Demographic data analysis used descriptive statistics by frequency distribution and percentages of correct answers to the pre-test and post-test.

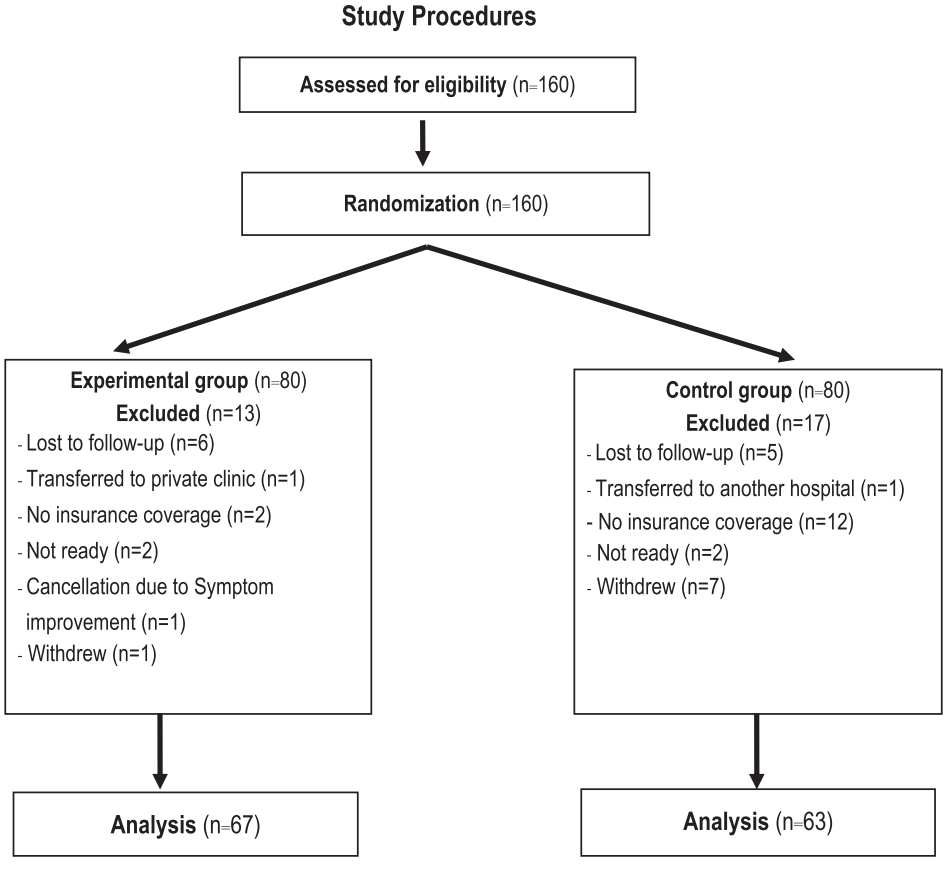

Figure 1 Flow diagram of study protocol

The difference in the need for a repeated colonoscopy following unclean bowel preparation was assessed using the chi-squared test. The different scores in the correct answers to the pre-test and post-test on patient knowledge before and after receiving advice and guidance was compared using independent t-test. Testing factors, such as gender, age, education level, chronic disease, correct answers on post-tests, and bowel preparation prior to colonoscopy in the experimental group to see whether it affected cleanliness was done using relative risk and 95% confident interval, which is the risk of developing an incident (or disease) from exposure to the factors.

Results

There is no difference between the general information of the experimental group and the control group (Table 1).

Even though the characteristics of people who received bowel cleanliness and repeat colonoscopy assessments by Aronchick bowel preparation scale (ABPS)[8] in the experimental group and control group did not differ, it was found that in the experimental group, the number of fair and poor intestinal cleanliness levels was 0.81 times that of the control group, which is approximately an absolute 13% difference. There was an inclination to do another bowel preparation, but the practitioner in charge tried to cleanse the intestinal tract to perform a diagnosis, so it took a long time, but did not affect the work plan.

It was found that for question 5 on food that can be eaten on the first and second day (soft foods, such as porridge (no vegetables), bread, fish, eggs, soy milk) was answered correctly by only 1.3% in the experimental

Table 1 Demographic and clinical characteristics of study population

Characteristics	Group	
	Experimental (n=67) n (%)	Control (n=63) n (%)
Gender		
Male	25 (37.3)	21 (33.3)
Female	42 (62.7)	42 (66.7)
Age (years), mean±SD	56.1 ± 9.9	53.6 ± 10.6
Education level		
Primary education	9 (13.4)	13 (20.6)
Secondary education	7 (10.4)	6 (9.5)
Higher education	32 (47.8)	30 (47.6)
Other	19 (28.4)	14 (22.2)
Chronic disease		
Hypertension/cardiovascular	25 (37.3)	14 (22.2)
Dyslipidaemia	16 (23.9)	12 (19.0)
Diabetesmellitus	9 (13.4)	4 (6.3)
Cancer	4 (6.0)	0 (0.0)
Gastrointestinal	5 (7.5)	7 (11.1)
Respiratory	0 (0.0)	1 (1.6)
Orthopaedics	3 (4.5)	2 (3.2)
Allergy	5 (7.5)	5 (7.9)
Other	4 (6.0)	2 (3.2)

Table 2 Intestinal cleanliness level and colonoscopy status (repeat vs. no repeat) in 130 colonoscopy patients

	Group		Total n (%)	*p-value*	RR (95% CI)
	Experimental (n=67) n (%)	Control (n=63) n (%)			
Intestinal cleanliness level					
Excellent	6 (9.0)	4 (6.3)	10 (7.7)		
Good	25 (37.3)	17 (27.0)	42 (32.3)		
Fair	32 (47.8)	36 (57.1)	68 (52.3)		
Poor	4 (6.0)	6 (9.5)	10 (7.7)		
Inadequate	0 (0.0)	0 (0.0)	0 (0.0)	0.1540	0.81 (0.61-1.07)
Colonoscopy					
No repeat colonoscopy	67 (100.0)	63 (100.0)	129 (100.0)		
Repeat colonoscopy	0 (0.0)	0 (0.0)	0 (0.0)		

A *p*-value < 0.05 indicates statistical significance

Abbreviations: ABPS, Aronchick Bowel Preparation Scale; RR, risk ratio; CI confidence interval

group and 2.5% in the control group (Table 3). Additionally, for question 2 on bowel preparation not needing laxatives but needing food that is easily digestible without fibers, the experimental group answered correctly more than the control group by 93.8% to 87.5% respectively. For other questions, the percentage of correct answers was over 80% similar (Table 3).

The average score of knowledge before and after receiving advice between the experimental and control group did not differ (Table 4).

For bowel preparation of patients in the experimental group, the actions that were followed by less than 90% are those relating to the preparation 1 day before the colonoscopy, namely only taking in fluids, which was at 80.3% (Table 5).

Table 3 Percentage of correct answers on the post-test

	Group		Total n (%)
	Experimental (n = 67) n (%)	Control (n = 63) n (%)	
Clean bowel preparation will make colonoscopy easier and make diagnosis and treatment easier	67 (100)	63 (100)	130 (100)
For bowel preparation, no laxatives have to be taken - only food that is easily digestible without fiber should be eaten	64 (95.5)	54 (85.7)	118 (90.8)
For bowel preparation before colonoscopy on days 1, 2 and 3, no vegetables and fruits should be eaten	63 (94.0)	58 (92.1)	121 (93.1)
For bowel preparation before colonoscopy, no meat should be eaten except for fish and crab	66 (98.5)	59 (93.7)	125 (96.2)
Food that can be eaten on day 1 and 2 of bowel preparation should be soft, easily digestible food, such as porridge (no vegetables), bread, fish , eggs, and soy milk	1 (1.5)	2 (3.2)	3 (2.3)
Food that can be eaten on day 3 of bowel preparation should be fluid, such as soup, boiled rice water, Ovaltine, milk, and sweet drinks without coloring	65 (97.0)	61 (96.8)	126 (96.9)
For bowel preparation for colonoscopy, patients do not need to take laxatives	67 (100)	63 (100)	130 (100)
After taking laxatives, milk and other food should not be eaten	60 (89.6)	58 (92.1)	118 (90.8)
Clean bowel preparation can help reduce risk of complications	65 (97.0)	59 (93.7)	124 (95.4)
No fluids and food of any kind should be taken after midnight before undergoing the colonoscopy	67 (100)	63 (100)	130 (100)

Table 4 Average knowledge score before and after receiving advice

Score	Group				*p*	p^{δ}
	Experimental		Control			
	Mean ± SD	(n = 67) Median (min-max)	Mean ± SD	(n=63) Median (min-max)		
Average score before advice	7.8 ± 1.1	8.0 (5-9)	7.7 ± 1.2	8.0 (4-10)	0.600	0.557
Average score after advice	8.7 ± 0.7*†	9.0 (6-10)	8.6 ± 0.8*†	9.0 (6-10)	0.225	0.229

Abbreviation: SD, standard deviation

A *p*-value < 0.05 indicates statistical significance

p-value by independent t-test; p^{δ} by Mann-Whitney U test; **p*-value < 0.001 paired *t*-test , †*p*-value < 0.001 Wilcoxon signed ranks test;

Table 5 Bowel preparation for colonoscopy in the experimental group

Preparation parameter	Able to n (%)	Reason not able to
2 days before - no fruits	66 (100)	
2 days before - only soft, easily digestible food	64 (97.0)	
1 day before - only fluid	53 (80.3)	Accidentally ate 1 piece of bread (n=1)
Taking laxatives	58 (87.9)	Vomiting (n=1)
Taking all laxatives	60 (90.9)	
Drank water after defecating	54 (81.8)	Nauseous (n=2) Forgot (n=1) Queasy (n=1)
Able to refrain from all food and fluid	65 (98.5)	
Score of actions undertaken before endoscopy, median (min-max)	7.0 (4-7)	

Table 6 Analysis for factors that significantly affect bowel cleanliness prior to colonoscopy

Factors	Poor bowel cleanliness		
	n (%)	RR (95% CI)	*p*-value
Gender			
Male (n=46)	2 (4.3)	1.000	0.308
Female (n=84)	8 (9.5)	2.1905 (0.48-9.89)	
Age range			
24-50 years (n=38)	2 (5.3)	1.000	0.512
51-75 years (n=92)	8 (8.7)	1.65 (0.37-7.42)	
Education level			
Higher than bachelor's degree (n=62)	3 (4.8)	1.000	0.258
Lower than bachelor's degree (n=68)	7 (10.3)	2.13 (0.58-7.87)	
Gastrointestinal tract disease			
Yes (n=12)	2 (16.7)	1.000	0.218
No (n=118)	8 (6.8)	2.46 (0.59-10.20)	
Diabetes			
Yes (n=13)	2 (15.4)	1.000	0.270
No (n=117)	8 (6.8)	2.25 (0.53-9.49)	
Hypertension/cardiovascular disease			
Yes (n=39)	4 (10.3)	1.000	0.474
No (n=91)	6 (6.8)	1.56 (0.46-5.2)	
Programs for experimental and control group			
Experimental group (n=67)	4 (6.0)	1.000	0.4522
Control group (n=63)	6 (9.5)	1.60 (0.47-5.39)	
Eating only fluids 1 day before colonoscopy			
Unable to do (n=13)	2 (15.4)	1.000	0.1394
Able to do (n=53)	2 (3.8)	4.08 (0.63-26.29)	
Drinking water every time after defecting			
Done (n=53)	1 (1.9)	1.000	0.020
Not done (n=13)	3 (25.0)	13.5 (1.53-118.8)	
Time between intervention and colonoscopy			
≤ 30 days	2 (5.0)	1.000	0.447
> 30 days	8 (9.0)	1.80 (0.40-8.09)	

A *p*-value < 0.05 indicates statistical significance
Abbreviations: RR, risk ratio; CI, confidence interval

The reason they were unable to follow the prescribed action was because they accidentally ate 1 piece of bread, drank water every time after defecation (81.8%), felt nauseous (2 persons), forgot (1 person), and vomited (1 person). With regard to taking laxatives, it was 87.9%.

There are factors that can affect the cleanliness of the bowel, namely gender, age, education level, chronic diseases such as digestive tract diseases, diabetes, hypertension, cardiovascular disease, and different programs for the control and experimental group (Table 6).

In the time from intervention to colonoscopy, it was found that none of the factors affected bowel cleanliness except for on drinking water after defecating. Those who were unable to do so were 13.5 times more likely to have unclean bowels compared to those who are able to ($p = 0.020$).

Discussion

From the results of the study on a structured bowel preparation program for patients who received bowel cleanliness assessments in the experimental group and control group, it was found that there was no difference in the cleanliness and need for repeat colonoscopies in both groups. In the experimental group, 46.3% had cleanliness levels of good or very good, while in the control group it was 33.3% ($p = 0.132$). There was also no difference in the average score for knowledge before and after receiving advice between the experimental group and control group. In addition, the researcher used the general information collected to analyze the relative risk (RR) for developing incidents (or disease) from exposure to factors in the general information. It was found that women have a higher risk of less clean bowels than men. Patients aged 51-75 years were also more likely to have less clean bowels than patients in the 24-50 years range. For education level, it was found that those who had an education level at less than a bachelor's degree had less clean bowels than those with higher than a bachelor's degree. It was also found that in the experimental and control group, chronic diseases affected bowel cleanliness. In order from high to low level of effects are digestive tract disease, diabetes, hypertension and cardiovascular disease.

When considered jointly with the results of the previous study, it can be seen that existing literatures on bowel preparation for colonoscopies have two approaches to bowel preparation, namely split dose regimen and same day regimen. Each regimen has their advantages and disadvantages. In the case of split dose regimen, patients have to take laxative the day before and morning of the colonoscopy. For the same day regimen, patients take laxative the morning before an afternoon colonoscopy. Both regimens have supporting studies saying that they are better than the other. This study cannot be used as data for the same day regimen, but may help increase the effectiveness of the split dose regimen. Nevertheless, more research is needed[5,6,7].

Although there was no difference in the results, the experimental group which received a structured bowel preparation program had a higher rate of good to very good bowel cleanliness assessments as compared to the control group that did not have such a program. The researcher believes that there are two key factors that affect bowel cleanliness. The first is related to the patient, namely their age, gender, education level, and chronic diseases. The second is the format of the program. Upon reviewing the research of Wei-Fan Hus[9], it was found that VDO and pictures illustrating the cleanliness of bowels made the cleanliness of bowel preparation in the very good level (21.8%-35.9%) and bad level (18.2%-15.9%).

The researcher agrees with the notion to adapt the aforementioned program and to have patients do self-assessments on whether they are ready for colonoscopy. From the study, it was also found that the control group did not see the importance of bowel preparation, and did not appreciate that a clean bowel is important in allowing doctors to perform diagnoses. This is a problem that requires further information and study.

Conclusion

Although there was no significant difference in the results, the experimental group that received a structured bowel preparation program was more likely to have very good or good levels of bowel cleanliness, higher than that of the control group that did not receive the structured bowel preparation program. These results can therefore be used to enhance the quality of bowel preparation. This study found that, for

bowel preparation before colonoscopy, each patient had different individual characteristics, making them more responsive to particular laxatives and bowel treatments. However, it remains that raising awareness in patients of the importance of bowel preparation for successful colonoscopies, increases the chances of finding tumors. On reducing the need for repeat colonoscopies resulting from unclean bowels, information is still insufficient from questioning patients on their defecation, such as a history of chronic constipation, and elderly patients having more difficulty digesting food with fiber than younger patients.

The limitation of this research is the low number of participants resulting from 30 patients not attending the scheduled colonoscopy after receiving advice in the experimental and control group.

Following analysis, the research team has the recommendations for a further study. The number of the control group and increasing follow up on patients about drinking water after taking laxatives. Some did not drink water due to experiencing abdominal discomfort, or drank water but only a small amount. Increasing follow up will help lead to cleaner bowel preparation for the next study.

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บทคัดย่อ **ผลของโปรแกรมการเตรียมลำไส้อย่างมีแบบแผนในผู้ป่วยที่มารับการส่องกล้องลำไส้ใหญ่: การศึกษาแบบสุ่ม**

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วัตถุประสงค์: สิ่งสำคัญที่มีผลต่อการวินิจฉัยและการทำหัตถการของการส่องกล้องลำไส้ใหญ่คือ ความสะอาดของลำไส้ การวิจัยนี้เพื่อศึกษาอุบัติการณ์การส่องกล้องซ้ำเนื่องจากเตรียมลำไส้ไม่สะอาดและประเมินความรู้ และการปฏิบัติตัว

วิธีการศึกษา: การศึกษานี้เป็นการศึกษาอุบัติการณ์ของการส่องกล้องซ้ำ การเตรียมลำไส้ไม่สะอาด และประเมินความรู้และการปฏิบัติในผู้ป่วยที่ได้รับการส่องกล้องลำไส้ใหญ่ เปรียบเทียบระหว่างสองกลุ่ม โดยใช้การทดลองแบบสุ่มแบ่งเป็นกลุ่มควบคุมจำนวน 63 คน ได้รับการดูแลตามปกติ ส่วนกลุ่มทดลองได้รับโปรแกรมเตรียมลำไส้ใหญ่จำนวน 67 คน เครื่องมือที่ใช้ในการเก็บรวบรวมข้อมูลคือแบบสอบถาม โดยใช้ค่าเบี่ยงเบนมาตรฐานไคสแควร์ การทดสอบค่าทีอิสระ ค่าความเชื่อมั่น

ผลการวิจัย: ไม่พบการส่องกล้องซ้ำในสองกลุ่ม แต่พบว่าในกลุ่มทดลองมีการประเมินความสะอาดของลำไส้ใหญ่ในระดับพอใช้และแย่น้อยกว่าคิดเป็น 0.81 เท่าเมื่อเทียบกับกลุ่มควบคุม (p = 0.1540) ซึ่งต่างกันประมาณร้อยละ 13 และคะแนนความรู้ความเข้าใจก่อนและหลังให้ความรู้ ตอบถูกใกล้เคียงกันคือมากกว่าร้อยละ 80 แต่มีประเด็นหัวข้อเรื่องอาหารที่รับประทานในวันที่ 1 และ 2 นั้น ตอบถูกเพียงร้อยละ 5 ใน Pretest และ Posttest ร้อยละ 1.9 ตามลำดับ แต่ในหัวข้อการปฏิบัติตัวเรื่องการดื่มน้ำตามทุกครั้งหลังถ่ายอุจจาระในกลุ่มที่ทำไม่ได้นั้น มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ (p < 0.05) คิดเป็น 13.5 เท่า เมื่อเทียบกับกลุ่มที่ทำได้ (p = 0.02)

สรุป: ถึงแม้ผลการทดลองที่ได้จะไม่มีความแตกต่างกัน แต่กลุ่มทดลองที่ได้รับโปรแกรมการเตรียมลำไส้อย่างมีแบบแผน มีแนวโน้มจะมีผลการประเมินการตรวจความสะอาดในระดับดีถึงดีมาก สูงกว่ากลุ่มควบคุมที่ผู้วิจัยเห็นว่าการให้คำแนะนำกับผู้ป่วยเพียงอย่างเดียวอาจไม่เพียงพอ ควรให้ผู้ป่วยประเมินระดับความสะอาดของลำไส้ด้วยตัวเอง จึงเป็นเรื่องที่จะเสนอแนะให้ผู้สนใจศึกษาในกลุ่มย่อยนี้ต่อไป