THE EFFECT OF COMFORT PROGRAM ON SATISFACTION, ANXIETY AND PAIN AMONG PATIENTS RECEIVING COLONOSCOPY

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ABSTRACT

The objective of this study wasto evaluate the effect of comfort program on satisfaction, anxiety and pain among patients who receive colonoscopy. A Quasi-experiment design was conducted among 158 patients including males and females with the age of 18 years or older in the Functional Examination Department of Bach Mai Hospital. They were divided equally into control and experimental groups receiving colonoscopy without sedation. Data were collected from the patients' hospital record, interview with the patients using the Mghaa-9 questionnaire, Hamilton Anxiety Rating Scale (HAM-A) and Numerical Rating Scale, ANCOVA, Mann-Whitney and Chi-square were used to analyze the data. There was significant difference of satisfaction and anxiety level between control and experimental group after colonoscopy ($p < .01$). Most of the patients in the experimental group were satisfied with colonoscopy services at very good and excellent levels (75.9%, 24.1%). They received a good bowel preparation expressed by the color of the fluid in their bowel during colonoscopy while the clearance of the patient's bowel in the experimental group was good and excellent level 65.82%, 22.78%, respectively. Pain levels increased to 4.96 ± 2.02 in the experiment group and 6.41 ± 2.10 in the control group. However, there were no differences between two groups. In conclusions, the comfort program showed that it was effective in many aspects and therefore nurses should sustain this program by training all nurses and health care personal as well as develop guideline with standing order prescription to release pain.

KEY WORDS : ANXIETY / COLONOSCOPY / COMFORT PROGRAM / PAIN / SATISFACTION /

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LIST OF ABBREVIATION

BMI	Body Mass Index
GHAA-9	The Group Health Association of America-9 Servey
HAM-A	Hamilton Anxiety Rating Scale
NRS	Numerical Rating Scale
VAS	Visual Analog Scale
WHO	World Health Organization

CHAPTER I
INTRODUCTION

1.1 Background and significance of the study

Colonoscopy is an investigation endoscopic procedure widely performed to screen or diagnose colorectal cancer and inflammatory bowel syndrome for patients (Ko, & Dominitz, 2010; Friedman, et al.,2013). Moreover, during colonoscopy procedure, patients could receive further investigation and treatment such as biopsy or lesion removal at the same time so that this procedure is widely accepted and used in every region of the world in particular, in the countries that show high incidence of colorectal cancer such as Finland (Ferlay, Autier, Boniol, Heanue, Colombet & Boyle, 2007). Although colonoscopy is an importance procedure giving benefit for patients on screening, early diagnosis and detection for colorectal cancer, patients undergoing this procedure always experience very unpleasant feeling. Before receiving colonoscopy, patients have to be prepared by bowel cleansing to make it possible to insert an instrument inside the colon through the rectum. Moreover, during colonoscopy the scope equipment has to be inserted until it reaches the certain point. The adequate amount of air has to be blown inside the colon to make the colon become wider and possible for the procedure. Patients therefore have to deal with pain and abdominal discomfort, distension before and during the procedure (Cotton & Williams, 2008; Rastogi & Wani, 2017). However, difference group of patients experience difference level of discomfort. Women experienced more pain and discomfort during colonoscopy than men because of the difference in anatomical structure (Takahashi, Tanaka, Kinjo & Sakumoto, 2005) and elderly patients reported less pain during colonoscopy comparing with the young because they had more pain tolerance (Ristikankare, 2000).

Bach Mai hospital is a leading health center of Vietnam Northern region. Each day, there are 200 visits for colonoscopy, in which 60 percent sedation and 40 percent non-sedation patients. In such the crowed-patient situation that seem to be overloaded for health staffs in the hospital in general and in this department in particular, patients usually suffer from discomfort like pain and bloating after having colonoscopy result in dissatisfaction with services (Functional Examination Department, Bach Mai Hospital, 2014).

The successful of colonoscopy depending on the cooperation between medical staffs and patients. This cooperation will bring successful result of colonoscopy process and pleasure for patients. Unfortunately, patients with colonoscopy without sedation usually experience negative feelings such as pain, anxiety that will make them fear of the procedure (Trevisani, Zelante & Sartori, 2014). These patients usually demonstrated high anxiety and would not cooperate with the procedure leading to dissatisfaction with the service. Dissatisfaction and pain are closely related to feeling of ashamed during the procedure is taken because the secret body part has to be exposed. They have to deal with both physical and emotional discomfort. Pain is associated with embarrassment, anxiety, and physical and emotional discomfort (Trevisani, et al, 2014). To make patients satisfy with colonoscopy, nursing intervention should be focused on promoting comfort, preventing pain and enhancing patients' confidence (Macintyre & Walker, 2010).

An importance quality indicator in health service is patient satisfaction because it reflects high quality of care according to patients' perspectives. According to hospital accreditation's view, patients' satisfaction is main focus in health care services. Any health care institutes are accountable for assuring that patients who receive care would be satisfy. The widely-accepted definition of patients' satisfaction is the perception of patients toward their experiences in health care services so that it is related to patients' cognition, emotion and perception. It is also associated with the environment, communication and relationship between patients and health care personnel (Triantafyllou, Cesare, Periklis, Konstantinos, Spyros, 2016; Maslekar, Hughes, Gardiner, Monson & Duthie, 2010).

Yacavone and the others conducted the study in 437 adult patients who came to Division of Gastroenterology and Hepatology of Mayo Clinics, USA to receive colonoscopy to test the psychometric property of the instrument to evaluate patients' satisfaction in colonoscopy. The results revealed 7 vital dimensions of endoscopy or colonoscopy satisfaction. Those included; (1) The skills of the physicians to perform colonoscopy, (2) The sufficiency of health care personnel to provide patients' comfort, (3) The caring style with support and health care personnel manners toward the patients during the procedure, (4) The understanding of patients toward the procedure can be obtained by simple explanation of the procedure and the expected sensation including discomfort or pain during the procedure, (5) The effective communication between physicians or nurses and the patients or their family member. This include the information about the purpose of the procedure, the expected outcomes as well as the opportunity of patients to discuss with physicians in the issues that they need further clarification, (6) The physical environment including the privacy of the examination room, the cleanliness, the climate and the appearance, and (7) The waiting time for the procedure which depending on the patients' appointment and the delay of the time form the appointment time (Yacavone, Locke, Gostout, Rockwood, Thieling & Zinsmeister, 2001). These 7 dimensions are comprehensive and cover patients' satisfaction and can be used as a standard scale to evaluate quality of colonoscopy in health care institute.

Pain control, patients attitude toward the procedure and the waiting time were associated with patients' satisfaction during colonoscopy (Maslekar, Hughes, Gardiner, Monson & Duthie, 2010). Satisfaction in colonoscopy services is a target of caring and hospital quality control assurance. In Bach Mai hospital, Hanoi, Vietnam, the target of patients' satisfaction is, including colonoscopy (Functional Examination Department, Bach Mai Hospital, 2014). The researcher has selected "comfort" to be the focused target of this present study. According to the definition of Kolcaba (2001), comfort refers to obtaining satisfaction through the achievement of human needs, relief from unpleasant feeling, feeling transcendence because of recovering from the very stressful health situation (Kolcaba, 2001). Initiating comfort measures focusing on patients' satisfaction will assure the patients on quality of care.

Abdominal pain and anxiety are common problems associated with colonoscopy procedure (Lee et al., 2004). Patients receiving colonoscopy always experience pain which leading to difficulty in performing colonoscopy. Now a day, pain control by various measures are provided during the colonoscopy such as oral or intravenous pain medication or general anesthesia. When patients suffering from pain from the procedures, they also have anxiety because they would feel uncertain and insecure. Moreover, lack of appropriate information is one of the causes that may lead to the anxiety and stress during the procedure (Bechtold, Puli, Othman, Bartalos, Marshall & Roy, 2009; Harikumar et al., 2006).

Normally, colonoscopy is the procedure that hardly bring patients' severe complications but it leads to unpleasant and stressful experiences (Ko & Dominitz, 2010; Bechtold et al., 2009). The feeling of being violated during the insertion of the colonoscopy tip through patients' anal sphincter is remarkable (Messman & Barnet, 2006). These patients are in vulnerable condition so that nurses' accountability should aim to provide them with comfort, ensure their safety and satisfaction (Harikumar et al., 2006). Although almost all patients experience pain during colonoscopy procedure, the intensity and severity of pain varies among each individual depending on patients' previous experiences, threshold, anxiety, past experiences on pain and pain management (Macityre et al., 2007). About 33% of patients underwent an un-sedated colonoscopy experience moderately or very painful by 33% of these 41% are women and 24% are men. (Holme et al., 2013). If patients' pain is not well managed, many adverse effects would occur. Effects from pain are multi-facets compose of physical changed, psychological alteration, emotional instability, fear, anxiety, cognitive impairment and behavioral changed (Brennan, Carr & Cousins, 2007; Mertin, Sawatzky, Diehl-Jones & Lee, 2007). Pain perception is the combination among brain, body, mind and behaviors (Taylor, Goehler, Galper, Innes & Bourguignon, 2010). Accordingly, among ones who receive proper and appropriated information related to the procedure, anxiety and pain is expected to decrease.

During the procedures, patients usually feel anxiety from fear of unknown, concerning about the investigation results and uncertainty conditions. Patients who

experience anxiety would react in various ways depending on their previous experiences, coping style and the amount of assisting resources. If anxiety is not well controlled, patients' stress will increase while patients' tolerance decrease resulting in non-cooperative with investigation procedure (Takahashi, et al.,2005). Prior to receiving colonoscopy, patients demonstrated anxiety related to the procedure, they also showed highly concern and expected that they would be unpleasant and would be exposed during the procedure (Ylinen, Vehviläinen-Julkunen, Pietilä, Hannila & Heikkinen, 2009). Ylinen, Vehvilainen-Julkunen & Pietila (2009) also confirmed that patients' anxiety was strong related to the unclear information about colonoscopy procedure and it had effect on patients' pain and discomfort.

Pain, discomfort, anxiety, unpleasant feeling and stress during the colonoscopy procedure lead to patients' dissatisfaction so that there have been many studies to reduce those problems. The measures include pharmacological, non-pharmacological and cognitive behavioral approaches (Harikumar, et al.,2006; Ylinen, et al., 2009). Providing patients with information is one measure that shows its effectiveness because it makes patients clearly understand the purpose and the steps of the procedures. This measure is congruent with the cognitive behavioral approach and can be used to prepare patients for receiving medical investigation procedure such as colonoscopy. Previous studies demonstrated positive patient outcomes including decreased pain level, reduced anxiety, feeling of security and satisfaction (Ylinen, et al., 2009; Arabulm, et al.,2012).

Patients who were appointed for colonoscopy investigation did not cooperate during the procedure because they did not receive sufficiency instruction on preparation. Accordingly, the bowel condition was not ready for colonoscopy. Patients had to receive repeated bowel irrigation until the investigation can be performed leading to longer waiting time (Friedman, et al, 2013). Earlier studies showed that information had a positive effect on undergoing a gastrointestinal endoscopy. Patients who were prepared by receiving information about the colonoscopy procedure from the video demonstrated less anxiety and were more satisfy. After the patients watched the video, physicians could easily encourage them for the follow up investigation in

the future. Furthermore, contents in the video could be tailored to suit individual patients according to their needs (Arabulm et al., 2012).

Satisfaction of patients during colonoscopy is challenge. It reflects quality outcome of health care services. In Bach Mai hospital, there are large numbers of patients receiving colonoscopy at functional examination department. It is overcrowded leading to very long waiting time with untidy environment. Accordingly, the researcher would like to apply comfort program composed with cognitive and behavioral education to achieve patients' positive outcomes.

1.2. Research question

Does comfort program have an effect on satisfaction anxiety and pain among patients receiving colonoscopy?

1.3. Purpose of the study

To evaluate the effect of comfort program on satisfaction anxiety and pain among patients receive colonoscopy.

1.4 Hypothesis

After the intervention, the satisfaction of patients receiving comfort program is higher than those of the controlled group.

1.5 Conceptual framework

Kolcaba's comfort theory is employed for a conceptual framework of this study. This theory comprises four components: Physical comfort, psychological, spiritual comfort, socio-cultural comfort and environmental comfort (Kolcaba, 2001;

Kolcaba & Steiner, 2000). It gives holistic perspective in providing nursing care while nurses are accountable to serve as "a comfort therapist". The comfort program comprises comprehensive activities; Providing information, reduce anxiety, improve environment, and pain reduction. The figure below shows that if comfort program is implemented, patients' satisfaction will be achieved, pain and anxiety level will be decreased.

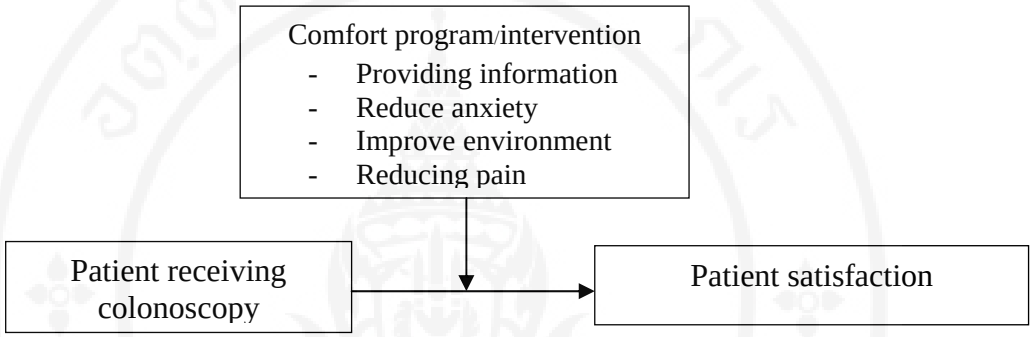

Figure1.1: Conceptual framework of this study adapted from Comfort Theory

1.6 Scope of the study

This study examines the effect of comfort program on satisfaction among patients who are 18 years or older receiving colonoscopy at Functional Examination Department, Bach Mai Hospital, Vietnam.

1.7 Expected outcomes and benefits

Health care teams can use this comfort program to promote satisfaction of patients receiving colonoscopy. Moreover, the comfort program can be used in the other group of patients in further study.

1.8 Definition of terms

Colonoscopy refers to the procedure whereby a physician inserts a viewing tube (colonoscope) into the rectum for the purpose of inspecting the colon. In this study, colonoscopy was performed by physicians in patients who came for their investigation appointment.

Patient satisfaction refers to patients' perception related to their needs. It reflects high quality of health services. In this study, Patient satisfaction was assessed using the modified GHAA-9 questionnaire which was derived from the Group Health Association of America-9 survey (Harewood, Yacavone, Locke &Wiersema, 2001). Higher score indicates higher satisfaction.

Comfort program refers to the program developed by researcher based on Kolcaba's Theory of Comfort (Kolcaba,2001) to advise the patients about the process of colonoscopy such as bowel preparation, intravenous infusion, colonoscopy position using leaflet and poster within the comfort, cleanliness and amenities of the reception area. In this study comfort program was developed by the researcher and research advisors to meet the needs of patients receiving colonoscopy.

Anxiety refers to a psychological and physiological state characterized by somatic, emotional, cognitive, and behavioral components (Seligman, Walker & Rosenhan, 2001). In this study anxiety was measured by Hamilton Anxiety Rating Scale (HAM-A) (Hamilton, 1959).

Pain refers to a comprehensive experience of sensation, physical awareness, perception and subjective interpretation of discomfort or unpleasant feeling (Kumar & Elavarasi, 2016). The response to pain comprise physiological, emotional and psychological response. In this study, pain was measured by Numerical rating scale (NRS) which is a widely accepted clinical pain scale developed by McCaffery in the year 1968 (Bijur, Latimer, Gallagher, 2003). NRS shew the number reflecting severity of pain from 0 to 10 in a horizontal line. Subjects were asked to verbally rate their pain on this scale with "0" equal to no pain and" 10" equal to worst possible pain.

CHAPTER II
LITERATURE REVIEW

This chapter provides a literature review of programs that effect satisfaction among patients receiving colonoscopy. The contents enhance the understanding of phenomena of satisfaction among patients receiving colonoscopy based on comfort theory as following 3 issues including the conclusion parts:

2.1 Problems among patients receiving colonoscopy

- 2.1.1 General knowledge about colonoscopy
- 2.1.2 The methods and the procedure of colonoscopy
- 2.1.3 The patients who need colonoscopy
- 2.1.4 The preparation process for colonoscopy
- 2.1.5 Colonoscopy and its effects on patients
- 2.1.6 Dissatisfaction of patients receiving colonoscopy

2.2 Comfort theory and patients receiving colonoscopy

- 2.2.1 General concepts of comfort theory
- 2.2.2 The comfort program for patients receiving colonoscopy

2.3 Concept related to patients' satisfaction

- 2.3.1 General concept related to patients' satisfaction
- 2.3.2 Colonoscopy and patients' satisfaction
- 2.3.3 Measurement of patients' satisfaction

2.4 Conclusion

2.1 Problems among patients receiving colonoscopy

2.1.1 General knowledge about colonoscopy

Colonoscopy refers to an investigation procedure widely performed for diagnosis and treatment of pathology related to colon and the distal part of small

intestine. It is commonly used for screening colorectal cancer as well as inflammatory bowel disease (Ko, & Dominitz, 2010; Friedman,et al, 2013). This procedure was initiated in the 1960's and has been continuously improved in its techniques and instruments to make it more effective and convenience for patients. In the year 2000 the American Society of Gastrointestinal Endoscopy (ASGE) recommended that colonoscopy should be used for colonic neoplasia surveillance and evaluation of any suspected abnormalities in the bowel (Yörük, et al, 2003).

The colonoscope is an instrument using for colonoscopy procedure. It composes of a fiber optic camera linking with a flexible tube and the special tip. This tube is used to insert through rectal sphincter into an anal canal and push until it reaches to the lesion in the large intestine. Colonoscopy procedure reach its completion while the tip of the scope pass through ileocaecal valve, ileal intubation, appendiceal orifice and triradiate fold (Hendry, Jenkins & Diament, 2007). Now a day, colonoscopy is considered as a gold standard procedure in diagnosis of intestinal polyps, other diseases in the intestinal tract and colorectal cancer. Comparing with contrast enema, colonoscopy gives more accurate diagnosis because the lesion can be seen through the fiber optic camera and the suspected adenoma or polyps can be biopsied to exam the histology. Hence the pathology can be early detected and the treatment can be early started leading to preference prognosis (Hendry, Jenkins & Diament, 2007; Tierney, Bevan, Rees & Trebble, 2016).

Colonoscopy has been advanced in its techniques, approach and equipment to make more accuracy in diagnosis and providing effective treatment. The physicians who are able to perform this procedure have to receive special training course and be mentored by the very expert colonoscopy physicians to make the procedure success and safety for patients (Hassan, et al., 2013).

2.1.2 The methods and the procedure of colonoscopy

2.1.2.1 Sedated or non-sedated colonoscopy

Colonoscopy can be performed under sedation or without sedation depending on choice and type of the patients, main purpose of the procedure and experiences of the physicians. With sedation, patients receive sedative couple with analgesic agents to make them calm and free of pain during the procedure. However,

patients have more chance to develop adverse events such as intestinal perforation, bleeding and respiratory complications from anesthetic agents (Yörük, et al, 2003). While the advantage of non-sedative colonoscopy is that patients can be appointed for an investigation on one day with the shorter length of time. After the procedure, patients would not have to stay in a waiting room for long time before being discharged from the hospital (Rastogi & Wani, 2017; Yörük, et al, 2003). The issue between sedated and un-sedated colonoscopy is still debatable. Many studies show that under sedation, patients feel more comfortable and relax while some studies show that there is no different between satisfaction among these 2 methods. This issue triggers further questions on how to make patients satisfy without sedation and lead to this present research.

2.1.2.2 Colonoscopy techniques and procedure

Colonoscopy procedure starts with positioning the patient on the left lateral position on the examination table. Left lateral position is recommended because the tube can be quicker inserted through the large bowel than the right lateral position. When the patient is ready, the physician will start to insert the colonoscope by which can be done by using water aided. There are 2 types of water-aided colonoscopy; water immersion and water exchange. These give patients advantage of less unpleasant feeling during the insertion process. Carbon dioxide (CO2) will be passed through the scope to distend the large bowel. This technique assists the scope move easier through the colon. Moreover, the physicians could observe the lesions in the bowel more clearly if lesion biopsy is needed it will be more easily performed and it can reduce failure rate of the procedure (Basan, et al, 2013; Rastogi & Wani, 2017). After the completion of assessment and lesion biopsy, the scope will be withdrawn. Patients will be monitored on their vital sign and any adverse events throughout the procedure and after the completeness of the procedure in the observation room (Yörük, et al, 2003).

In Bach Mai hospital, there are two options for the patients with colonoscopy, sedation and non-sedation. The sedated method is preferred by patients who are intolerant of the colonoscopy procedure and can pay for the service. Regardless of the anesthetic methods, the procedures for colonoscopy preparation and performance are the same.

2.1.3 The patients who need colonoscopy

Colonoscopy is an acceptable investigation procedure widely used among patients in various health problems related to large intestine and colon. Following are types of patients and the objectives on using colonoscopy.

2.1.3.1 Screening in adults who demonstrate average risk on colorectal cancer. For adults age over 50 years, it is recommended that they should receive colonoscopy for the baseline screening. Thereafter, they should receive this procedure in every 10 years because there are evidences to support that using colonoscopy for screening can early detect risk of colorectal cancer effectively (The American Society for Gastrointestinal Endoscopy, 2011).

2.1.3.2 Investigate and treatment of intestinal polyps. Patients who are diagnosed of intestinal polyps are ones who have risk for developing colorectal cancer. Colonoscopy with polypectomy is highly recommended for detection, definite diagnosis as well as performing treatment at the same time (Yörük, et al, 2003; Rastogi & Wani, 2017).

2.1.3.3 Follow up investigation in colorectal cancer patients after operation. Colonoscopy is considered as a routinely investigation for those aforementioned group of patients. According to the standard recommendation, patients with colorectal cancer should receive 6 to 12 months colonoscopy follow up. If the result is negative 2 to 3 years follow up is further recommended (The American Society for Gastrointestinal Endoscopy, 2011).

2.1.3.4 Investigation in individuals who have family history of intestinal cancer. A person who has family history of intestinal cancer or colorectal cancer is at risk for colorectal cancer. Colonoscopy is therefore would offer good opportunity for early detection. The procedure can be performed for every 1 to 3 years if the result is negative (Rastogi & Wani, 2017).

2.1.3.5 Investigation and treatment of patients with inflammatory bowel disease. In patients who are suspected of inflammatory bowel disease colonoscopy is a gold standard investigation and at the same time treatment can be performed during the procedure (Rastogi & Wani, 2017).

2.1.3.6 Identify the bleeding sites among patients with bleeding per rectum. Patients with lower intestinal bleeding usually have bleeding

lesions at the lower part of large intestine. Accordingly, using colonoscopy is convenience and effective to confirm the severity and location of lesion as well as to perform treatment to stop bleeding (Rastogi & Wani, 2017).

2.1.3.7 Differential diagnosis among patients who present with the chief complain of chronic abdominal pain or discomfort, chronic diarrhea or constipation and other dysfunction of bowel movement (Rastogi & Wani, 2017). Colonoscopy is therefore become an investigation procedure for detecting abnormality of gastrointestinal tract. Moreover, using colonoscopy is very cost effectiveness because when abnormality is early detected, the treatment can be done effectively and the prognosis is good (Yörük, et al, 2003).

2.1.4 The preparation process for colonoscopy

Colonoscopy is a demanding process, in order to have successful result, patients must have bowel preparation prior to the procedure. Effective bowel preparation will help physicians to have more accurate view and the reliable diagnosis will achieve. On the other hand, inadequate level of cleansing is an obstacle on colonoscopy (Voiosu, et al., 2014).

2.1.4.1 Advise patients to eat low fiber diet

Two to three days before the colonoscopy procedure, patients are advised to eat low fiber diet to prepare empty intestine. In particular, one day before the procedure, clear liquid diet such as clear soup is recommended. On the day of colonoscopy, patients have to drink adequate amount of water, sugar tea, coffee without milk. Also, they are advised to avoid alcohol drink. However, patients who have colonoscopy under aneasthesia, they are advised to take nothing per oral 6 hours before the procedure (Hassan, et al., 2013).

2.1.4.2 Advise patients to take Polyethylene glycol solution

To clean and clear the bowel by remove all stool from the colon, polyethylene glycol solution is recommended. Patients are advised to take this solution for laxative effect. The other regimen is take polyethylene glycol solution with magnesium citrate in case of patients without abnormal renal function (Hassan, et al., 2013).

2.1.4.3 The preparation process should be taken at least 3 days before the procedure. The written information in form of patients' booklet should be provided with clear verbal communication and a channel for patients to ask for further information. Information related to adverse effects from bowel preparation such as nausea, abdominal discomfort is very significant and should be included in the patients' booklet (Hassan, et al., 2013).

Beside the above procedures, routine care for patients include;

(1) Recording patients' vital signs and any abnormality at the beginning of the procedure to be baseline data.

(2) Asking patients or an authorized person to sign the consent form.

(3) Advising patients to urinate before the procedure starts to empty the urinary bladder.

2.1.5 Colonoscopy and its effects on patients

Overall risk from colonoscopy is relatively low if patients are well prepared, physicians are expert and have tremendous experiences, nurses can perform close monitoring during and after the procedure and the procedure is conducted under the aseptic environment (Hendry, Jenkins & Diament, 2007; Ko & Dominitz, 2010). Although, there has been reports of intestinal perforation, intestinal bleeding but it is very rare. The effect on patients delayed recovery is rarely found. Patients do not require hospital stay so that they can return home on the day of the procedure (Hassan, et al., 2013).

In regard to the health care expense, colonoscopy might affect some patients who did not have full coverage for the expense of this procedure. In Vietnam, if colonoscopy has to be performed under sedation, patients have to pay out of pocket for the extra expense. However, comparing with the advantage of the investigation procedure, it is cost effectiveness.

Anxiety is commonly found in patients receiving colonoscopy. It is found at the phase before the procedure, during the procedure and after the procedure. Patients' anxiety is associated with many factors such as receiving insufficient information about the procedure and expected symptom during the procedure. If anxiety is not well managed, patients would not be cooperated during the procedure

and pain couple with unpleasant would occur (Carter, Topolski & Hatzigeorgiou, 2013; Voiosu, 2014). Furthermore, after the procedure while patients are waiting for the histopathology result, they always feel very anxious and very uncertain (Lucio, Angelo, Sergio, 2014).

2.1.6 Dissatisfaction of patients receiving colonoscopy

Dissatisfaction among patients receiving colonoscopy derive from various factors. Some factors can be independently managed by nurses but some factors have to be managed with multidisciplinary team. Those factors include;

2.1.6.1 Pain

Pain during the procedure occur when the endoscope tip is pushed through the rectal sphincter and while the tube pass through the colon. Pain level during this process will be prominent if patients are not cooperated with the procedure because the rectal sphincter and the orifice muscle will become constricted then the physician has to force creating more painful. Patients also experience abdominal pain in the recovery room after the procedure. Pain level has been measured by asking the subjective feeling of patients or record the amount of pain medications used in order to reduce pain (Harikumar, et al, 2006).

2.1.6.2 Discomfort

Patients receiving colonoscopy usually experience abdominal distension during and after the procedure. Some patients complained distention at epigastric area because of carbon-dioxide insufflation during the procedure and this unpleasant feeling will remain after the procedure. Patients who receive sedative agents might experience side effects after the procedure such as nausea and respiratory complications. These will lead to discomfort and dissatisfaction (Lucas, Erin, & Maida, 2009).

2.1.6.3 The waiting time

If the bowel preparation is not effective, patients have to take laxative agents repeatedly until the bowel is clear otherwise the physician cannot perform colonoscopy. Patients who have to take laxative several times have to wait for longer time comparing with ones who have their bowel well prepared (Chartier, Arthurs & Sewitch, 2009).

2.1.6.4 The environment around the investigation area

Environment affects patients' emotion and feeling. Untidy and dirty environment make patients unpleasant and have negative impression leading to dissatisfaction about the service. In particular, the toilet areas have to be kept clean and ready to use at any time because patients have to use the toilet during the preparation phase before the procedure (Chartier, Arthurs & Sewitch, 2009).

2.2 Comfort theory and patients receiving colonoscopy

As earlier mentioned in the contents under the item 2.1, during colonoscopy procedure patients often experience unpleasant feeling, pain, abdominal discomfort and anxiety. Severity of these problems lead to dissatisfaction with health service. The nursing intervention programs such as providing appropriate information, reduction of anxiety, effective pain control and arranging good and desirable environment could make patients become comfort and satisfy.

2.2.1 General concepts of comfort theory

Comfort theory is a middle range theory developed by Kolcaba in 1991 by analyzed and synthesized the empirical published evidences related to comfort. This theory has been revised and re conceptualized to make it more clear and feasible to apply in research and practice. According to Kolcaba "comfort" refers to the state of being strengthened by obtaining the individual needs in 3 aspects related to comfort including being relieved, being eased and being transcendence. Kolcaba further stated that those needs have to be met under the 4 contexts including physical, psychospiritual, social and environmental context (Kolcaba, 2001). When comfort theory is employed into research or practice, it would cover 4 components; physical comfort, psycho-spiritual comfort, socio-cultural comfort and environmental comfort. The approach of comfort theory is vital for nursing profession because it reflects wholistic approach which cover all facets of patients' requirements (Kolcaba & Steiner, 2000). Comfort theory has been utilized in many group of patients from the acute illness stage until the rehabilitative and end of life stage. When it was applied in research, the concept associated with comfort include pain, anxiety, unpleasant feeling

and satisfaction. When comfort theory was tailored to an interventional program, the intervention has to cover, patients physical, psycho-spiritual and socio-cultural aspect as well as the surrounding environment.

2.2.2 The comfort program for patients receiving colonoscopy

Kolcaba' comfort theory is very suitable to use as a conceptual framework in caring of patients receiving colonoscopy. The comfort program for these patients emphasizes on 4 dimensions as follow;

2.2.2.1 Providing patients with physical comfort regimen

It refers to positioning the patients in relax position during and after the procedure (Devitt, Shellman, Gardner & Nichols, 2011). Collaborate with the physicians to prescribe analgesic drugs to reduce pain during colonoscopy. Providing continuous monitoring patients' pain, discomfort from abdominal distension and nausea. If those physical symptoms are detected, pharmacological or non-pharmacological management have to be performed (Eeva-Riitta, 2010). Non-pharmacological pain management such as listening to soft music can help reduce pain during and after the procedure because music can distract patients' focus from the procedure and make them become more relax. Moreover, listening to the music relevant to patients' preference could reduce anxiety which has an effect on pain (Harikumar, et al, 2006; Bechtold, et al, 2009).

2.2.2.2 Providing patients with psycho-spiritual comfort regimen

This refers to establishing the relationship with the patients. The good relationship starts with being openness to the patients. Offering patients time and opportunity to ask questions and discuss on their concerns. Providing information to clarify colonoscopy procedure. This will assure patients on the procedure and help reduce their anxiety. Spiritual need should be assessed and support should be given according to patients' spiritual needs. Being close with the patients during the procedure can increase their psycho-spiritual comfort. Provide patients with necessary information related to the procedure will decrease patients' anxiety, make them clearly understand about the situation and the symptoms that would occur. Information can be

provided in various ways depending on the characteristics of the patients (Arabulm et al., 2012; Carter, Topolski & Hatzigeorgiou, 2013).

2.2.2.3 Providing patients with socio-cultural comfort regimen

This refers to giving patients social support relevant to their requirements. Instrumental support should be provided as well as other significant resources. Assess patients' cultural preference and provide them with cultural support such as their own cultural believe. Nurses should be very sensitive on patients cultural believe, respect and providing individualized care. Using positive and supportive body language can help increasing socio-cultural comfort too (Russell, et al., 2013).

2.2.2.4 Providing patients with environmental comfort regimen

This refers to preparing calm and clean environment in the investigation room. Keeping the environment and the toilet clean will give patients more pleasant feeling. A well-designed environment is not only influence the psychological state of patients but also increase the satisfaction with their surroundings, the hospital itself and the care provided (Russell, et al., 2013).

It can be concluded that the comfort program according to Kolcaba' comfort theory should cover 4 dimensions of regimen as above mentioned. These 4 approaches would reduce patients' pain, anxiety and finally lead to patients' satisfaction. In particular, this comfort approach is very suitable to apply among patients who receive care in the acute care clinical settings such as in patients at the waiting room or recovery room of operating department or in patients at the investigation department such as colonoscopy (Wilson & Kolcaba, 2004).

2.3 Concept related to patients' satisfaction

2.3.1 General concept related to patients' satisfaction

Patients' satisfaction is a key indicator to reflect good health care outcomes (Gill & White, 2009). It refers to patients' perception, subjective assessment on the overall care services receive at one point of time. Although, positive care outcomes cannot be solely measured by satisfaction, now a day it still remains one

importance indicator in quality assurance and hospital accreditation. Gill and White conducted intensive literature review on patients' satisfaction and summarized that there are 5 theories explaining patients' satisfaction in health care.

(1) The theory of congruency. According to this theory, satisfaction would occur when patients' needs or requirements are congruent with the health care services provided.

(2) The theory of value expectation. According to this theory, satisfaction would occur when patients receive the requirements relevant to what they have expected. In this theory, it is believed that satisfaction related with patients' perception, attitude and cognition.

(3) The theory of determinants. According to this theory, satisfaction is strongly related to personal preference so that it is a subjective response of a person. In regard to this theory, satisfaction differs from person to person depending on their past experiences and their interpretation. When providing care to the patients, health care providers have to concern about their background and their individual difference.

(4) The multiple models theory. In this theory, satisfaction can be mediated by social factors. The expectation of patients on health care service depend on social expectation and social norm.

(5) The health care quality theory. This theory is formulated by Donabedian in the year 1980(Gill & White, 2009). Donabedian stated that patients' satisfaction is the principle outcome of the interaction between health care personnel and patients. He emphasized that patients' satisfaction is very subjective depending on how the patients make judgement on the quality of care they receive. According to his ideology, patients' satisfaction strongly reflects the quality of health care services.

Gill and White further stated that satisfaction on health care services cover 4 areas of quality including interpersonal quality, technical quality, environmental quality and administrative quality. Interpersonal quality refers to the interaction or interpersonal relationship between health care personnel and patients. In order to obtain this dimension, effective communication is a key concept. Technical quality refers to the skill or expertise of health care personnel. Patients always expect to receive effective care from the reliable and skillful health care personnel to make sure that the outcomes of care will be effective. Environmental quality refers to atmosphere

in the health care settings. Atmosphere is very important when providing care because it influences patients' perception, emotion and feeling. Administrative quality refers to a good operation system of the health care organization. The health care settings with good operational system would have strategies on time management related to service provided to patients. Decreased waiting time for receiving treatment is a good indicator of good operational system and can solve problem of patients overcrowded in health care system (Gill & White, 2009).

2.3.2 Colonoscopy and patients' satisfaction

There are many factors related to patients' satisfaction with colonoscopy. Those include factors related to procedural pain and discomfort, prolonged waiting time, feeling of uncertainty about the investigation result, feeling of embarrassment from being exposed during the procedure and fear of unknown. The study of Ingrid and the others revealed that patients who had to wait for receiving treatment in the hospital setting for very long time reported that they felt underprivilege, low self-identity and being hostile with the service (Ingrid, Lars & Annsofie, 2012). Following are selected studies elaborating phenomena of patient's satisfaction with colonoscopy.

Chartier and the others conducted an integrative review of 15 cohort studies on patient satisfaction with colonoscopy. The results of the review showed that most of patients were very satisfy with colonoscopy and were willing to return for the further colonoscopy for their follow up investigation. Comparing colonoscopy with other investigation procedure such as barium enema or computer tomography (CT) most of patients stated that they prefer to receive colonoscopy than the other investigative procedure. There were small numbers of patients who report dissatisfaction on colonoscopy. Those complained that during colonoscopy, they felt very discomfort and unpleasant (Chartier, Arthurs & Sewitch, 2009).

The study conducted in a tertiary care hospital in Malaysia by Chan and Goh among 426 patients underwent colonoscopy found that bowel preparation and waiting times are 2 main factors related to satisfaction of patients. The researchers further stated that in order to make patients become satisfaction with the colonoscopy procedure, the waiting time for appointment should not exceed 1 month, while the

waiting time on the day of colonoscopy should not be more than 1 hour. The result from this study contributed to standard practice of colonoscopy (Chan & Goh, 2012).

Denters and the others conducted a descriptive study among 69 patients receiving colonoscopy and 34 physicians who performed colonoscopy at the Academic Medical Centre in Amsterdam, The Netherlands. The aim of their study focused on factors related to patients' satisfaction in colonoscopy in patients' perspective and comparing with physicians' perspective. The results of this study revealed that the concerns of physicians and patients were different. While physicians' concern emphasized on patients' physical symptom such as pain, abdominal cramps and other complications, patients concerns emphasized on being respected as a person, receiving adequate information and having a chance to discuss about their concerns with the physicians. The researchers further stated that the physicians underestimated the importance of having patients engage in decisions regarding the colonoscopy procedure (Denters, M.J., Deutekom, Derkx, Bossuyt, Fockens & Dekker, 2012).

One of the most important study on satisfaction of patients with colonoscopy is the study of Yacavone and the others (Yacavone, et al., 2001). From their study, they describe 7 domains of satisfaction with colonoscopy which include patients' satisfaction in expert skill of colonoscopists, comfort procedure, caring of health care personnel, sufficiency information, good communication, good environment and short waiting time. It was suggested from their study that to make patients satisfy with colonoscopy, the measures should be focused on those 7 aforementioned domains.

2.3.3 Measurement of patients' satisfaction

Measuring patients' satisfaction with care is vital because it can provide health care personnel with the real need from patients' perspectives. Hence it would help improve quality of health care services. There are many instrument for measuring patients' satisfaction. Some instruments are general instruments while some are more specific to each group of patients. The instrument to measure patients' satisfaction with colonoscopy that has been widely used in research and practice settings is the modified GHAA-9 questionnaire. This instrument is concise, validated and can be applied to various settings (Harewood, Yacavone, Locke & Wiersema, 2001). The

original GHAA-9 questionnaire comprises seven core items while “The modified GHAA-9 questionnaire” (Harewood, Yacavone, Locke & Wiersema, 2001; American Society for Gastrointestinal Endoscopy, 1999) comprises 10 items. Three more items were added to cover whole picture of patients undergoing colonoscopy. In this study and researcher used “The modified GHAA-9 questionnaire”. All 10 items were scored with 5 value Likert scale, with 1 representing "poor" and 5 representing an "excellent" satisfaction rating. The maximal possible total satisfaction score was 50.

2.4 Conclusion

It can be summarized that patients undergoing colonoscopy have to deal with many problems which would affect their satisfaction with the procedure. The Kolcaba’s comfort theory is suitable to use as a framework because it covers the patients’ need in physiological, psycho-spiritual, socio-cultural and environmental aspects. The comfort program aimed to increase patients’ satisfaction by providing information, reducing anxiety, improving environment, and reducing pain.

Accordingly, the comfort program was tailored as followed detail. Providing information guidelines included the information for bowel preparation and colonoscopy process by using posters of stool color and leaflets with short, diagramed form easy to understand for patients. These posters and leaflets were distributed to patients directly, hanged on waiting room wall and toilet wall. Reducing anxiety was archived by some activities for example explaining for patients the important steps in pre- and post- colonoscopy, listening to music. The patient’s anxiety was evaluated using Hamilton Anxiety Rating Scale. Improving environment was planned to make change to being clean, fresh, warm, safe and friendly atmosphere in area of colonoscopy room, waiting and reception room including toilets. Reducing pain was obtained by repositioning and breathing guiding patient during colonoscopy, fentanyl 0.1 mg in 2 ml injection to patients when having doctor’s prescription, and guiding patient to reduce gases in abdominal. Visual Analog Scale was used to assess pain level of the patients after colonoscopy.

CHAPTER III
METHODOLOGY

3.1 Research design

Quasi-experiment design was used to evaluate the effect of comfort program on satisfaction among patients received colonoscopy.

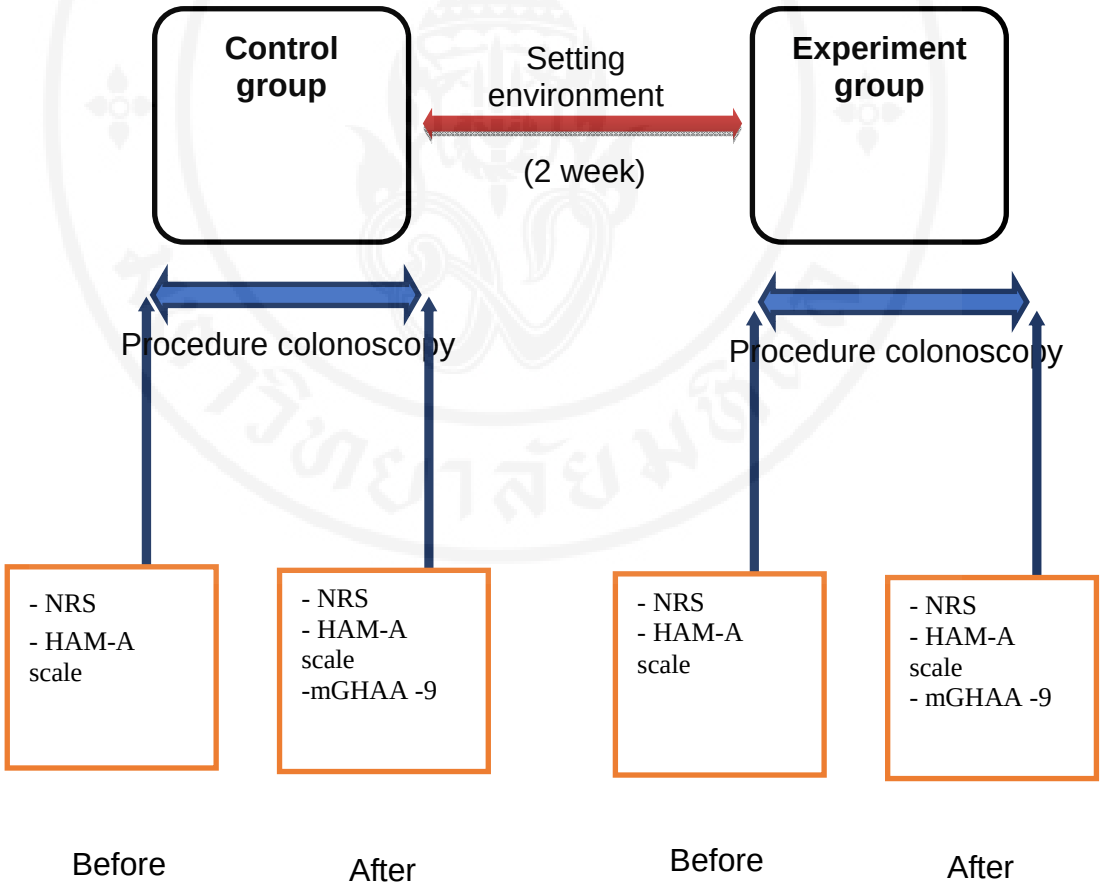

Figure 3.1 Quasi-experiment design

3.2 Population and sample of the study

3.2.1 The population of this study.

The population of this study was the patients with age from 18 years old or above who received colonoscopy without sedation at the Functional Examination Department of Bach Mai Hospital, Hanoi, Vietnam.

3.2.2 The sample of the study sample.

The sample of the study was selected form the Outpatients receiving colonoscopy at the Department according to the following criteria:

The inclusion criteria are as follow:

1) Outpatients receiving colonoscopy without sedation at the Department.

2) Be able communicate with the researcher in Vietnamese.

3) Be willing to participate in the study.

The exclusion criteria

1) Patients who did not complete the colonoscopy.

The Termination criteria

1) Patients who were intolerant with the colonoscopy while receiving the procedure even health staff attempted to support.

2) Patients who had complications such as unstable vital sign such as Blood Pressure (BP) over 160/90 mmHg or BP under 90/60 mmHg, bleeding, or perforation during colonoscopy.

Sample size:

The sample size in this study was calculated by using G*power 3.1.9.2 program to determine the minimum number of participants needed for Quasi-experiment design (Faul, Erdfelder, Buchner, & Lang, 2009). The researcher test ed effect of comfort program on satisfaction of patients who receive colonoscopy without sedation. Based on G*power analysis and the study of Katseesung et al., (2015) about preparing bowel and bowel quality in colonoscopy patients, three parameters are required including I) the level of significance a= 0.05, 2) the power of the statistical test (Power 1-p= 0.85), 3) the effect size (ES= 0.48) from the control group (x = 6, SO = 2.24) and the experiment group (x = 6.88, SO = 1.31). So, the sample size at least

158 samples. After adding for drop out sample, total number of each group is 79 persons.

3.3 Setting

This research was conducted at the Functional Examination Department of the first special – category comprehensive general hospital of Vietnam, Bach Mai hospital, which is an intensive health facility at the highest technical level. Bach Mai hospital established in 1911. With nearly 2000 beds, 2 Institutes, 8 Centers, 21 Clinical departments, 6 Paraclinical departments, 9 Functional departments, 1 Nursing college school. Its modern system of equipment and facilities has also helped fulfill its responsibility in performing a number of important tasks of the country's health sector: Providing care and treatment at the highest level, training, scientific research, providing guidance and direction to health facilities of lower levels, disease and epidemic prevention and control, international cooperation, health economic management. The Functional Examination Department receives 30 cases per day and 700 cases of colonoscopy without sedation per month. Healthcare services are providing for inpatients and outpatients from 7:30 AM to 4:30 PM including receiving patients, preparing patients such as bowel clean before the procedure and assistance the patients during the process, monitoring and taking care of the patient after the process.

The control group was performed colonoscopy with standard care including:

1) Nurse helped patients to Register and wait for examination

2) Nurse verbally guided them how to prepare bowel.

3) Nurse explained how to do the endoscopy, advised possible complication/accident for endoscopy and encouraged patients for prevent anxiety.

4) Nurse assisted the doctor to take place the endoscopy. During the process, nurses guided the patients for positioning, direction, and breathing.

5) Nurses helped patients to recover after endoscopy in recover room.

3.4 Instruments

There were instruments for data collection and experimental instrument as follow.

3.4.1 Instruments for data collection: The instruments used for data collection included 4 parts as follows:

Part I: Questionnaire demographic data of the patients

The researcher developed this questionnaire by herself. The demographic data of the patients had 6 items including age, gender, occupation, and educational level, illness history and previous treatment information.

Part II: Hamilton Anxiety Rating Scale (HAM-A)

The HAM-A was one of the best and widely used scale designed for measuring the level of anxiety symptoms. It contains 14 items which were defined by a series of symptoms that could measure both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). Each item was scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56, where < 17 indicates mild severity, 18–24 mild to moderate severity and 25 –30 moderate to severe (Hamilton, 1959). HAM- A demonstrated internal-consistency reliability 0.93 and test-retest reliability 0.97, respectively (Kobak, 1999).

Part III: Numerical Rating Scale (NRS)

Numerical rating scale (NRS) was a common pain scale being used in clinical practice as well as in clinical research. This pain scale was developed by McCaffery in the year 1968 and had been tested for its reliability in various group of patients including patients with acute and chronic pain, showing the Cronbach's Alpha ranging from .8 to .91 (Koneti & Jones, 2016). NRS shew the number reflecting severity of pain from 0 to 10 in a horizontal line. Subjects were asked to verbally rate their pain on this scale with "0" equal to no pain and" 10" equal to worst possible pain.

The values on the pain scale correspond to pain levels as follows:

1-3 = mild pain

4 - 6 = moderate pain

7 - 10 = severe pain

Part VI: Satisfaction for endoscopy

In this study, patient satisfaction was assessed using the modified GHAA-9 questionnaire which was derived from the Group Health Association of America-9 survey (Harewood, Yacavone, Locke & Wiersema, 2001). The seven core items of the modified GHAA-9 survey comprised of the questionnaire used in this study, and researcher add three questions to adapt with her research. This questionnaire comprised of 10 questions regarding the satisfaction of patient and quality provided to the patient, both assessing by the patient itself via giving the score for each question. All 10 items were scored with 5 value Likert scale, with 1 representing "poor" and 5 representing an "excellent" satisfaction rating. The maximal possible satisfaction score was 50 (American Society for Gastrointestinal Endoscopy, 1999). Higher score indicated higher satisfaction. In study of Sánchez del Río et al. (2005), they found that mGHAA-9 has high reliability with Cronbach's Alpha of 0.82.

Quality of bowel preparation:

During investigation, the doctor checked on colonoscopy imaging (Appendix D) and evaluate the bowel quality both experimental and control group.

3.4.2 Experimental instrument for Comfort program.

Comfort program was designed with 4 targets: Providing information; reducing anxiety; improving environment; reducing pain which all to enhance patient satisfaction. (i) Providing information guidelines included the information for bowel preparation and colonoscopy process by using posters of stool color and leaflets with short, diagramed form easy to understand for patients. These posters and leaflets were distributed to patients directly, hanged on waiting room wall and toilet wall. (ii) Reducing anxiety was archived by some activities for example explaining for patients the important steps in pre- and post- colonoscopy; listening to music. (iii) Improving environment was planned to make change to being clean, fresh, warm, safe and friendly in area of colonoscopy room, waiting & reception room and toilets (iv) Reducing pain was obtained by repositioning and breathing guiding patient during colonoscopy; fentanyl 0.1 mg in 2 ml injection to patients when having doctor's indication; guiding patient to reduce gases in abdominal after colonoscopy (Appendix F).

3.5 Instrument Reliability and Validity

3.5.1 Instrument Reliability

Vietnamese versions of HAM-A, mGHAA-9 were tested for internal consistency reliability before conducting the actual data collection. These questions were pilot test on 30 patients who had the qualifications like the samples, and used with 158 sample. Then, the scores were taken to find the reliability of each questionnaire.

Scale	N of Items	Cronbach's Alpha (n = 30)	Cronbach's Alpha (n = 158)
Hamilton Anxiety Rating Scale	14	0.82	0.76
Satisfaction for Endoscopy	**9**	0.79	0.73

3.5.2 Instrument Validity

Vietnamese version of the Hamilton Anxiety Rating Scale and mGHAA-9 were verified by 5 experts. Their content validity was inspected and suggestions were made. Linguistic changes were made to them before being tested on 30 samples to assure their understanding of the contents.

3.6 Data collection

The data collection was conducted in the following sequence:

1) Preparation research assistant

A Research assistant in this project was two-year experienced nurse in the Function Examination department of Bach Mai hospital. Researcher trained her/him about objective and details of project focusing on her/his role for approach voluntary subject, how to include and exclude by inclusion and exclusion criteria, describing to participant with simple word for understanding also process of signing consent form

(2) The researcher assistant self-introduced, made a relationship with the patients. The researcher assistant introduced to patients the objective of study, data collection procedure and asked for the research cooperation. In addition, researcher assistant asked patient to sign consent form. The patients were volunteer in the study. The researcher collected some demographic data from medical record form.

(3) The researcher organized private room to interview the patients or do questionnaire by themselves. Then, researcher used five questionnaires for data collection. Questionnaires were 1) demographic data of the patients had 13 questions, 2) Hamilton Anxiety Rating Scale (HAM-A) has 14questions, 3) Numerical Rating Scale (NRS) had 1 questions, 4) Modified GHAA- 9 Questionnaire has 12 questions. Total questionnaire had 40 questions and the time is about 20 minutes.

(4) The doctors were asked for rating the quality of bowel preparation from colonoscopy imaging and fill out the questionnaire. (Appendix D)

3.7 Protection of human rights

This study was conducted base on the protection human rights. The participants were asked to participate in this study by volunteer. The researcher explained the purpose of the study, the research procedure, benefit, risks, types of questionnaire, length of time for completing questionnaire, and right to refuse participation in study anytime. The participants who agreed to participate were informed and assured that the data would be kept confidentially and would be reported only as a group data. Informed consent was signed by all participants. During interview or use questionnaires if patients don’t want to participate in this study they can stop in any conditions. The patients got the same standard care after withdraw from the study. There is no any affection for caring. If the patients had unstable conditions for example pain, bleeding, fatigue, the researcher would stop to interview. The researcher would immediately contact with doctors who had response to take care the patients, the researcher would take care until patients already stable. The data from withdraw or termination were excluded. The participant data were kept in confidentially by using code.

3.8 Data analysis

Data analysis used program computer to the following statistics.

1. Frequency, percentage, mean and standard deviation were used to describe the general characteristics and medical of the samples.

2. The descriptive statistics in term of frequency, percentage, mean and standard deviation and range were used to describe study variables, including satisfaction, pain and anxiety of patients receive colonoscopy.

3. ANCOVA for anxiety, Mann-Whitney for non-normal distribution of pain and satisfaction and Chi-square tests for demographic data and doctor's satisfaction were used. The significant level of testing, alpha was 0.05.

CHAPTER IV
RESULTS

4.1 General characteristics of the participants

General characteristic of the participants was shows in table 4.1. Total sample included 158 patients enrolling in this study. The majority of patients were female (51.9%) with the average age was 29-49 years old (45.6%)). The most of patients was married (91.3%), finished junior (58.2%) (table 4.1).

Table 4.1 General characteristics of the participants

Variable	Total		Control group		Experiment group		P value
	Number (n=158)	%	Number (n=79)	%	Number (n=79)	%	
Gender							**0.633**
Male	76	48.1	36	45.6	40	50.6	
Female	82	51.9	43	54.4	39	49.4	
Age (years)							**0.959**
18-29	15	9.5	7	8.9	8	10.1	
29-39	36	22.8	17	21.5	19	24.1	
40-49	36	22.8	19	24.1	17	21.5	
≥ 50	71	44.9	36	45.6	35	44.3	
	Mean±SD: 47.85 ± 14.59 Min: 19Max:81		Mean±SD: 48.66 ± 14.87 Min:22Max:80		Mean±SD:47.04 ± 14.36 Min: 19Max: 81		

Table 4.1 General characteristics of the participants (cont.)

Variable	Total		Control group		Experiment group		P value
	Number (n=158)	%	Number (n=79)	%	Number (n=79)	%	
Married							**0.808**
Married	144	91.1	72	91.1	72	91.1	
Single	9	5.7	5	6.3	4	5.1	
Divorce	1	.6	1	1.3	0	0	
Widow	4	2.5	1	1.3	3	3.8	
Education level							**0.034**
Primary	3	1.9	0	0	3	3.8	
junior high school	89	56.3	43	54.4	46	58.2	
high school	21	13.3	14	17.7	7	8.9	
College	18	11.4	5	6.3	13	16.5	
Bachelor	26	16.5	16	20.3	10	12.7	
master and higher	1	.6	1	1.3	0	0	
Occupation							**0.001**
Famer	51	32.3	16	20.3	35	44.3	
Housewife	8	5.1	7	8.9	1	1.3	
Tire	26	16.5	17	21.5	9	11.4	
Officer	19	12.0	6	7.6	13	16.5	
Other	54	34.2	33	41.8	21	26.6	
Location of residence							**0.036**
Urban	47	29.7	30	38.0	17	21.5	
Rural	111	70.3	49	62.0	62	78.5	
Insurance							**0.36**
Insurance	17	10.8	17	21.5	22	27.8	
pay by themselves	139	88.0	62	78.5	56	70.9	
Company	2	1.3	0	0	1	1.3	
Income (USD)	Mean±SD: 28.76 ± 16.48 Min:0.00Max: 86.96		Mean±SD: 27.44± 18.52 Min:0.00Max:86.96		Mean±SD: 30.08 ± 14.14 Min:0.00Max:65.22		**0.016**

4.2 Impacts of intervention on Numerical Rating Scale

One hundred fifty eight participants were divided into two groups (79 peoples each) named control group and experiment group. The control group was treated with normal procedure as usual and the experiment group was treated with comfort program. The experiment results were analyzed based on mostly three variables including Numerical Rating Scale (NRS) for pain assessment, Hamilton Anxiety Rating Scale (HAM-A) for anxiety assessment before and after colonoscopy with Satisfaction Survey for satisfy assessment to address the question whether pain or anxiety has an impact on the patient's satisfaction. The net results should be calculated by the difference between before (pre) and after (post) the colonoscopy. Therefore, we calculated the differences in pain and anxiety from pre- to post- named D_{NRS} and D_{HAM} respectively (D_{NRS}=NRS*pre* - NRS*post;* D_{HAM}=(HAM-A) *pre*–(HAM-A) *post*.

The pain of participants was described by Numerical Rating Scale before (pre) and after (post) colonoscopy in both control and experiment group (the intervention group) in table 4.2. Data of pain scale was not normal distribution ($p<0.05$), therefore Mann-Whitney test was used for addressing the difference of D_{NRS} between two groups. The NRS score in control group before and after colonoscopy was 5.91±2.113 and 6.41±2.097, respectively. That score in experiment group was similar from both before and after colonoscopy with 4.367±1.902 and4.962±2.015. Obviously, in this study, there was no significant difference in pain score between control and experiment group in both pre and post colonoscopy condition ($p=0.321$). The same result was observed for the difference NRS before and after (D_{NRS}) ($p=0.183$).

Table 4.2 Summary the NRS score in control and experiment groups

VAS	Control group	Experiment group	Mann-Whitney U	Wilcoxon W	Z	P
Mean D_{VAS} ± SE	0.494±0.059	0.595±0.055	2788.500	5948.500	-1.332	**0.183**
Mean VAS_{pre} ± SD	5.91±2.113	4.367±1.902				
Mean VAS_{post} ± SD	6.41±2.097	4.962±2.015				
N	79	79				
Mean Rank	40	119				
Sum Rank	3160.00	9401.00				

4.3 Impact of intervention on HAM-A score

In addition to pain assessment, all participants were examined for anxiety level by answering the questionnaire HAM-A. The data was normal distribution by Shapiro-Wilk test ($p>0.05$) following analyzed by ANCOVA test. Table 4.3 showed that there were significant differences in HAM-A score before (pre), after (post) and D_{HAM} between control and intervention group ($p=0.000$). Before colonoscopy, the HAM-A score of patients in control group was quite high with 28.91±5.851 in comparison with that of experiment group 18.27±4.227. After colonoscopy, the anxiety score of patients in control group seemed not change despite in experiment group that was reasonable change to only 8.82±4.607

Table 4.3 Impact of intervention on HAM-A score

Group	HAM-A score (mean±SD)		D_{HAM}=(HAM-A)*pre*–(HAM-A)*post* (mean±SE)
	Pre	***Post***	
Control	28.91±5.851	30.53±6.706	-1.620±0.769
Experimental	18.27±4.227	8.82±4.607	2.215±0.389
P2	**P=0.000 (ANCOVA)**		

4.4 Evaluation of patient's Satisfaction

The results in table 4.4 shows that there was significant difference in satisfaction score between two groups (p=0.000). This result was obtained by using Mann-Whitney test because the data did not have normal distribution. After the intervention, patients in experiment group were more satisfy with all steps of the colonoscopy procedure with score of 38.48±2.281 than that in control group with mean score of 22.96±2.261. ‘

Table 4.4. Evaluation of Satisfaction between control and experiment group

Satisfaction	Control group	Experiment group	Mann-Whitney U	Wilcoxon W	Z	P
Mean ± SD	22.96±2.261	38.48±2.281	0.000	3160.000	-10.905	**0.000**
N	79	79				
Mean Rank	40	119				
Sum Rank	3160.00	9401.00				

4.5 Correlation of pain, anxiety and satisfaction

The results in table 4.5 showed that there was no significant correlation between pain and anxiety (p=0.126) as well as between pain and satisfaction (p=0.167). However, we observed the correlation between anxiety and satisfaction (p=0.000) in all participants.

Table 4.5 Correlation of Difference in Pain, Difference in Anxiety and Satisfaction in all participants

Variable	**D_{NRS}**	**D_{HAM}**	**Satisfaction**
D_{NRS}	1.00		
D_{HAM}	-.122	1.00	
Satisfaction	-.110	.370**	1.00

**. Correlation is significant at the 0.01 level (2-tailed).

Correlation of pain, anxiety and satisfaction in control group (A) and experiment group (B).

Table 4.6 (A&B) showed that in both groups there was strong correlation between NRS-pre and NRS-post, between HAM-A pre and HAM-A post as well as between NRS and HAM-A results. In contrast, we did not observed any correlation between pain (NRS), anxiety (HAM-A) with satisfaction in control group (table 4.6A). However, in experiment group we did observe a clearly negative correlation between anxiety (HAM) with satisfaction of colonoscopy patients (Table 4.6B). That means the more patients were anxiety, the less patients becomes satisfy.

Table 4.6 Correlation of pain, anxiety and satisfaction in control group (A) and experiment group (B).

A. Control group	**NRS pre**	**NRS post**	**HAM-A pre**	**HAM -A post**	**Satisfaction**
NRS pre	1.00				
NRS post	.969**	1.00			
HAM-A *pre*	.293**	.317**	1.00		
HAM -A *post*	.365**	.343**	.413**	1.00	
Satisfaction	.005	.041	.088	-.025	1.00
B. Experiment group	**HAM-A pre**	**HAM-A pre**	**NRS pre**	**NRS post**	**Satisfaction**
HAM-A pre	1.00				
HAM-A pre	.664**	1.00			
NRS pre	.366**	.452**	1.00		
NRS post	.344**	.421**	.951**	1.00	
Satisfaction	-.437**	-.538**	-.198	-.162	1.00

**. Correlation is significant at the 0.01 level (2-tailed).

4.6 Evaluation patient's feedback.

The results expressed in table 4.7 using Chi-square test. The patients with intervention in this study mostly seemed to be prefer to answer "probably come back" or "certainly come back or willing to recommend to others" by nearly 90 percent, only around 10 percent of participants had negative feedback. In contrast, patients in control group mostly chose "not wishing to come back unless lack of alternatives" and "probably come back" by more than 83 percent in which 60 percent of negative feedback. These led to significant difference between control and experiment group in patient's feedback ($p<0.05$). The good sign was that patients with intervention prefer to come back our Department in this study.

Table 4.7 Patient's feedback

Criteria	**Control (n,%)**	**Experimental (n,%)**
Certainly never come back	4(5.06)	1(1.27)
Not wishing to come back unless lack of alternatives	45(56.96)	7(8.86)
Probably come back	21(26.58)	48(60.76)
Certainly come back or willing to recommend to others	9(11.39)	23(29.11)
Chi-Square Tests	Cramer's V = 0.54; P < 0.05	

4.7 Color of bowel fluid and bowel clearance assessment

According to doctors performed colonoscopy questionnaire, result in table 4.8 showed that color of fluid in patient's bowel was light orange and yellow by nearly 90 percent and around 68 percent in experiment group and control group, respectively. In control group, still more than 30 percent of participants having bowel with dark color in comparison with only 10 percent having that in experiment group. Chi-square test was used to address the significant difference between color of patient's bowel

reached $p<0.05$ with$X^2 = 15.83$. From this results, it reflexed that experimental or intervention group was well-prepare bowel than control group.

Table 4.8 Color of fluid in patient's bowel

Criteria	Control (n,%)	Experimental (n,%)
Dark and murky	10(12.66)	1(1.27)
Dark orange	9(11.39)	3(3.8)
Brown and murky	6(7.59)	4(5.06)
Light orange	15(18.99)	11(13.92)
Yellow	39(49.37)	60(75.95)
Chi-Square Tests	$X^2 = 15.83$; $P<0.05$	

In line with color fluid of bowel assessment, the clearance of patient's bowel was also evaluated by the doctors. Chi-square test result showed there was clearly difference in ranking on bowel preparation quality in control and experiment group ($X^2 = 40.67$; $P<0.05$). Forty percent of patients in control group had "good or excellent" bowel in comparison with that of 86 percent in experiment group. In control group the number of dirty bowel including "a bit dirty and very dirty" still was high with 30 percent, on the other hand this number in experiment group only 7.6 percent .

Table 4.9 The clearance of patient's bowel

Criteria	Control (n, %)	Experimental (n, %)
Excellent	18(22.78)	52(65.82)
Good	13(16.46)	16(20.25)
Acceptable	24(30.38)	5(6.33)
A bit dirty	15(18.99)	5(6.33)
Very dirty	9(11.39)	1(1.27)
Chi-Square Tests	$X^2 = 40.67$; $P<0.05$	

CHAPTERV
DISCUSSION

5.1 The effect of comfort program on satisfaction of the patients

The result of this study showed that the experiment group has significantly higher score of satisfaction with colonoscopy than that of control group ($p<.001$) in overall picture. Some domains such as doctor's and nurses' manner toward the patients, adequate explanation, receiving appropriate information and environment of the department were prominent. In regard to environment, the patients in experimental group reported that waiting room, examination room and toilet were very clean, comfortable and convenience.

The explanation is that, in the comfort program the approach focusing in 4 dimensions of comfort; physical, psycho-spiritual, socio-cultural and environmental comfort. These 4 dimensions are congruence with the concept of satisfaction as proposed by Gill and White (2009).

Evaluation of patient's satisfaction is an important issue of healthcare services and is a quality measure of provided service. This assessment has been found to be helpful in improving standards of health investigation departments including performance of endoscopists, caring behaviors of health care personnel, atmosphere surrounding endoscopy area, that are factors built the reputation of endoscopy departments in long term. Patient's satisfaction also affects perception of the population at large towards endoscopic services and can have significant impact on patients' compliance with endoscopic procedures regardless their previous experiences with colonoscopy.

Questionnaires on satisfaction or quality perceived by patients allow to identify the most common causes for dissatisfaction. In all 8 questions (about appointment date, length of time spent waiting at the office for the procedure, the personal manner (courtesy, respect, sensitivity, friendliness) of the physician, the nurses and the other support staff who involve in patient's colonoscopy, the technical

skills (thoroughness, carefulness, competence) of the endoscopist, adequacy explaining of what was done for patient, patients were provided information appropriately: about bowel preparation prior colonoscopy, adverse or complication of colonoscopy (leaflet, poster), environment of waiting room, examination room, toilet… are clean, comfortable and convenience) more patients in experimental group satisfied with the colonoscopy procedure with very good level. Long time of waiting in front of colonoscopy room was rated fair and just good in 95.7% of control patients. It is similar to Sanchez Del Rio and the others' results in a multicenter study. The most frequent aspects were waiting time for an appointment and discomfort during the examination. Significant differences were found among centers in the overall satisfaction score (questionnaire score) ($p < 0.001$) and for the rate of perceived problems ($p < 0.001$) (Sanchez Del Rio, et al (2005). And only patients in experimental group satisfied at excellence level in some steps including convenient environmental, consult of health care staff, personal manner of the nurses and the other support staff, technical skills of endoscopists. The similar result was showed in Azmi's study in an Asian tertiary care hospital with seven hundred patients by using interview technique. It was found that waiting times for appointment and on gastroscopy day, and discomfort during procedure comprise of over 90% of unfavorable responses. Satisfactory response diminished to undesirable level when waiting times for appointment and on gastroscopy day exceeded 1 month and 1 hour, respectively. Satisfaction scores were higher for waiting time for appointment but lower for personal manner of nurses/staff and explanation given during phone-back interview (Azmi, et al, 2012).

Mc Entire and the others concluded that patients undergoing colonoscopy highly prioritize aspects of care relating to the interaction with the endoscopist and the procedure itself. Environment factors were considered to be less important. These findings may assist in service redesign based on patients' expectation and value within their own pathway which reflects the approach of patient-centered care (McEntire, Sahota, Hydes & Trebble, 2013).

Del Río and the others studied about patient's satisfaction after undertaking a colonoscopy, the results described that negative appraisal percentages for each of the seven questions were: waiting time until the appointment, 9.3%;

waiting time on the day of examination, 3.5%; explanations, 3.9%; personal manner of staff, 0.5%; personal manner of the physician, 0.6%; discomfort, 3.5%; overall rating, 1.9%. The vital few found by Pareto analysis were questions regarding waiting time for appointment and adequacy of explanations regarding procedure. These questions accounted for 61% of the total number of problems encountered by patients (Del Rio, et al, 2007).

About overall rating of the visit, only one patient (1.3%) in control group in the study rated poor fulfillment and the contrast is predicted between the two groups. In control group, 97.5% patients' fulfillment is fair and good, in experimental group 76 % of patients' fulfillment is very good and the rest is excellent. It is for a second time confirmed that the changes in colonoscopy procedure get good effect in patient's satisfaction.

Published studies of patient attitudes to their endoscopy procedure indicated the importance of ensuring that endoscopists and their staff would monitor and prevent patient discomfort, have expert technical skill and effectively communicate with their patient relating to the procedure and results. Designing environmental factors, including noise, privacy and the single-sex environment, are considered to have less value. There are contrasting views on patient attitudes to waiting times for the procedure. Implementing patient-centered care in endoscopy requires an understanding of what patients want from their healthcare experience. The results from available studies suggest implications for current practice that relate to the training and practice of the endoscopists and their staff (Tierney, et al., 2016).

After experiencing a colonoscopy procedure, patient's attitude to comeback is variation between the two groups. Though receiving better conditions in all steps of colonoscopy process one patient in experimental group and 4 patients in control group are certainly never come back. Most of patients in control group (56.96%) are not willing to come back unless lack of alternatives, differently, whereas, in experimental group,most of patients (56.96%) are probably come back and 29.11% of patients are certainly come back or willing to recommend to others. To systematically review the literature and conduct a pilot study of patient satisfaction with the colonoscopy experience, Lucas analyzed all cohort studies from January 1997 to August 2008 in the Medline database that measured either patient satisfaction with

colonoscopy, patient willingness to return for colonoscopy under the same conditions or patient preference for colonoscopy compared with other large bowel procedures were identified. Of the 29 studies identified, 15 met the inclusion criteria. Consistently, the vast majority of patients (approximately 95%) were very satisfied with their colonoscopy experience. (Chartier, Arthurs & Sewitch, 2009).

Although, patients are willing to come back if they are indicated for another colonoscopy, they still have discomfort. And it is proved in Konstantinos's research. And in June 2016, Konstantinos and colleges prospectively assessed long-term patient satisfaction of gastrointestinal endoscopic procedures of 501 patients in a Greek Academic endoscopy facility. The result shows that more than 97% of the participants would repeat the procedure in our facility and would recommend our endoscopy service, at all three assessments. Pareto analysis identified waiting time until the appointment and on the day of the examination, discomfort during and after the endoscopy, time to obtain the pathology report and overall management of the patient problems as the issues requiring improvement. No predictor of high satisfaction score has been identified. No serious late adverse events were reported.

5.2 The effect of comfort program on level of pain

The findings illustrated that pain score was no difference between control and intervention groups before and after intervention with ($p<.05$). The cause of this condition was due to the protocol of pain control. Nurses had to follow to the doctor's prescription and some doctors did not give a fentanyl or any pain control medication in both experimental and control groups. This result was similar to Holme's results, which colonoscopies were perceived as moderately or very painful by 33% of the patients (41% of the women, 24% of the men, $p < 0.001$) (Holme et al, 2013). Moreover, Xiaolu Wu Carter carried out in eighty-one patients and the findings described that patients with more anxiety was significantly associated with higher levels of abdominal pain after the procedure ($p<0.01$) and still recalled more painful from the procedure after one week later

Control and reduce of discomfort and pain during colonoscopy was considered to be a high priority by patient. Main methods for reducing pain and anxiety, to break the trinomial colonoscopy, pain and fear by intervention program comfort (Trevisani & Zelante, 2014). Before experiencing a colonoscopy, patients in experimental group received a consult from researcher, therefore, they could fell less pain than the control group both after and before colonoscopy procedure. After experiencing a colonoscopy, patients in both groups control and experimental felt more pain and the difference between pre and post colonoscopy is statistical significance ($p < 0.05$).

However, there were many factors that influenced on patient's felling of pain. In 2007, Chung implicated these factors in the published article "Patient factors predictive of pain and difficulty during sedation-free colonoscopy: a prospective study in Korea". Multivariate logistic regression analyses revealed that older age, lower body mass index, previous hysterectomy, diarrhea, 1st time colonoscopy and anxiety were predictors of patient pain. Older age, lower body mass index and previous hysterectomy were predictors of difficulty of intubation (Chung, et al, 2007). In the same year, Park DI indicated factors affecting abdominal pain during colonoscopy in his study. Chi-squared analyses demonstrated that female gender, younger age (<or=40 years), presence of symptoms of inflammatory bowel syndrome, history of previous abdomino-pelvic surgery, poorer bowel preparation, longer insertion time (>480 s), technically difficult insertion, and lower body mass index (BMI) are factors associated with uncomfortable procedure. Multivariate analysis demonstrated that younger age, female gender, lower BMI, difficulty of examination, and previous gynaeco-pelvic surgery in female gender are independent factors associated with discomfort during colonoscopy (Park, et al, 2007).

5.3 The effect of comfort program on patient anxiety

Patients undergoing a colonoscopy might experience anxiety prior to the procedure over patient discomfort. Whilst the anxiety may be short lived, this may result in a feeling of increased discomfort during and after the procedure.

There was statistically significant difference of HAM - A score in patients between control and experimental group in two periods, before and after undergoing colonoscopy ($p < 0.05$). The anxiety was indifferent, even minor increased after colonoscopy in the control group (28.91 versus 30.53, $p = 0.38$). In contrast, in the experimental group, HARS score declined sharply 10 points after the intervention (18.27 versus 8.82, $p < 0.05$). In one research, Ylinen, Vehvilainen-Julkunen&Pietila (2009) also found patient state anxiety to be heightened pre-colonoscopy, which had a significant impact on how difficult and painful the procedure was perceived by patients.

The reason for diminishing the anxiety in patients in experimental group before and after undergoing a colonoscopy is that they received a guide from nurses about colonoscopy produce before undergoing a colonoscopy and likewise they were put in more convenient environmental with large waiting room, listening to music in time of waiting, clean toilet. This result is coincided with findings in many researches using method of guiding patients before colonoscopy to reduce patient's anxiety and improve quality of colonoscopy produce. A study of Arabulm et al. found that providing information for patients by video can decreases anxiety and abdominal pain during the procedure. It also increases procedure success as well as patient satisfaction levels. Informing by video also provides a platform from which physicians can more easily persuade patients for checks in the future should it be deemed necessary. Another finding of this study is that physicians should pursue different informational strategies considering the patient's gender (Arabulm et al., 2012).

In conclusion, after applying comfort theory, patient was more satisfied and less anxious. These results proved that comfort theory had good impact on patient's satisfaction and support Kolcaba's Comfort Theory that Physical comfort, Psycho-spiritual comfort, Socio-cultural comfort, & Environmental comfort Resulted to patients' satisfaction.

CHAPTER VI
CONCLUSION

6.1 Conclusion of the study

Quasi-experiment design was used to evaluate the effect of comfort program on satisfaction among patients received colonoscopy who aged 19– 81 years old in Functional Examination Department from August to October, 2016. Comfort theory was utilized as a framework of this study. The sample size in this study was calculated by using G*power version 3.1.9.2 program to determine the minimum number of participants needed for Quasi - experiment design. The sample calculation yielded 158 samples. The research setting was Functional Examination Department, a center specializing in Bach Mai hospital, Hanoi, Vietnam.

After obtained approval from Institutional Review Board of Nursing faculty, Mahidol University and Institutional of Review Board of SMP, Vietnam National University, Hanoi, Vietnam. The researcher used 3 instruments; the demographic data questionnaire, Numerical Rating Scale (NRS), Hamilton Anxiety Rating scale (HAM – A) and Satisfaction for endoscopy was assessed using the modified GHAA-9 questionnaire which was derived from the Group Health Association of America-9 to collect data. All instruments were tested for their validity and reliability as clearly explained in chapter 3. Cronbach's alpha coefficient of HAM -A and satisfaction for endoscopy were .76, .73, respectively. The 158 sample were selected according to the inclusion criteria. The researcher collected data by herself from 8.00 am to 4.30 pm every day until the sample reached the target of the studied sample size. For each sample the researcher spent 20 minutes on interviewing and collected some data from their patients' records. During data collection, there was no adverse event among the sample. All sample recruited in the study remained throughout the study process with no attrition.

Data analysis was conducted by using SPSS computer program. The descriptive statistics in terms of frequency, percentage, mean and SD and range were

used to describe study between 2 groups study. ANOCOVA for anxiety, Mann-Whitney for non-normal distribution of pain and satisfaction and Chi-square tests for demographic data and doctor's satisfaction were used. The significant level of testing, alpha is 0.05.

The findings are summarized as follows:

Total sample includes 158 patients. The majority of patients is female (51.9%). The average age was 47.85 ± 14.59. The most of patients was married (91.3%), finished junior high school education (56.3%), worked many kind of jobs and lived in rural (70.3%). The socical conditions of patients in this study is low.

In all 8 questions about appointment date, length of time spent waiting at the office for the procedure, the personal manner of the physician, nurse and the other support staff, the technical skills of the physician who performed your procedure, adequacy explaining colonoscopy, patients were provided appropriately information about bow preparation prior colonoscopy, adverse or complication of colonoscopy, convenient environment before, during and after the colonoscopy, more patients in experimental group satisfied with the colonoscopy procedure with very good level. No patients in the study rated excellent satisfaction with appointment date and duration of waiting. Overall rating of the visit, only one patient (1.3%) in control group in the study rated poor fulfillment and the contrast is predicted between two groups. In control group, 97.5% patients' fulfill mentis fair and good, in experimental group 76 % of patients' fulfill mentis very good and the rest is excellent. It is again confirmed that the changes in colonoscopy procedure get good effect in patient's satisfaction. Each step in colonoscopy has it effect patient's satisfaction. Patients received better conditions pre, during and post colonoscopy had more satisfactory trend.

After experiencing a colonoscopy procedure, patient's attitude to comeback is variation between two groups. Though receiving better conditions in all steps of colonoscopy process one patient in experimental group and 4 patients in control group are certainly never come back. Most of patients in control group (56.96%) are not willing to come back unless lack of alternatives, differently, most of patients in experimental group (56.96%) are probably come back and 29.11% of patients are certainly come back or willing to recommend to others.

Most of patients in experimental group were good bowel preparation expressing by the color of fluid in their bowel was yellow (above 70%) while less than 50% patients in control group had yellow fluid in bowel during a colonoscopy. Endoscopes also rated the clearance of patient's bowel in experimental group more excellent than in control group (65,82%, 22,78%, respectively). Shorter waiting time, more convenient atmosphere around the colonoscopy and received more detail instruction about bowel preparation help patients have better bowel preparation.

Pain score was no difference between control and intervention groups before and after intervention with ($p<.05$). The cause of this condition was due to the protocol of pain control.

Patients undergoing a colonoscopy may experience anxiety prior to the procedure over patient discomfort. Whilst the anxiety may be short lived, this may result in a feeling of increased discomfort during and after the procedure. There is statistic significant difference of anxiety level between control and experimental group. The anxiety is indifferent and in significantly increased after colonoscopy in the control group(28.91 versus 30.53, $p = 0.38$). In contrast, in the experimental group, the anxiety level is sharply deceased 10 points after the intervention (18.27 versus 8.82, $p < 0.05$). Patients in experimental was less anxious than control group because they received a guide from nurses about colonoscopy produce before undergoing a colonoscopy and they also put in more convenient environmental with large waiting room, listening to music in time of waiting, clean toilet.

6.2 Implications in nursing practice

6.2.1 The comfort program for patients undergoing colonoscopy should be implemented in functional examination center to improve quality of patients care. Hence it will lead to good image of the hospital.

6.2.2 Make the comfort program sustain by informing the policy makers of the hospital. This will urge them to announce as the policy or the standard of the hospital.

6.2.3 Distribute knowledge related to the comfort program to other health care personnel in other departments of the hospital to encourage them to apply this comfort program in other group of patients.

6.2.4 Develop the training program for junior health care staffs on comfort program. Hence the comfort manner will become a culture of the nursing department.

6.2.5 Distribute knowledge of the comfort program to cover other hospital in Vietnam to improve quality of health care services and patients' satisfaction.

6.3 Implications in research

6.3.1 This comfort program should be tested for its effectiveness in other group of patients by using quasi-experimental study.

6.3.2 Multi sites research to test effectiveness of the comfort program should be conducted.

6.3.3 In the further research, long term outcomes such as the next follow up visit should be measured.

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APPENDICES

APPENDIX A
LIST OF EXPERTS

1. Dr Nguyen Manh Truong PH. D

Head of functional examination department, Bachmai Hospital, Vietnam.

2. Dr. Kieu Van Tuan MD. PhD

Functional examination department, Bachmai Hospital, Vietnam

3. Dr. Nguyen Van Ngoc

Functional examination department, Bachmai Hospital, Vietnam.

4. Mrs. Bui Minh Thu

Head of nurse department, Bachmai Hospital, Vietnam.

5. Mr. Nguyen Manh Hung

Nurse of functional examination department, Bachmai Hospital, Vietnam.

APPENDIX B
CERTIFICATE OF APPROVAL

CERTIFICATE OF APPROVAL
From
Institutional Review Board Faculty of Nursing Mahidol University

COA No.IRB-NS2016/366.0807

Title of Project:	**THE EFFECT OF COMFORT PROGRAM ON SATISFACTION, ANXIETY AND PAIN AMONG PATIENT RECEIVING COLONOSCOPY**
Project Number:	**IRB-NS2016/29.0703RS1**
Principle Investigator:	**Mrs.Truong Thi Thuy Houng**
Name of Institution:	**Faculty of Nursing Mahidol University**
Approval includes	1) IRB-NS Submission form version received date 4 July 2016 2) Participant Information sheet version date 4 July 2016 3) Consent form version date 4 July 2016 4) Questionnaire version received date 4 July 2016

Institutional Review Board Faculty of Nursing Mahidol University is in full compliance with International Guidelines for Human Research Protection such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Type of Review:	**Full Board Review**
Date of Approval:	**08 July 2016**
Date of Expiration:	**07 July 2017**

Signature of Chair: Fongcum Tilokal
(Associate Professor Dr. Fongcum Tilokskulchai)
Chair

Signature of Dean, Faculty of Nursing Yajai Sitthimongkol
(Associate Professor Dr. Yajai Sitthimongkol)
Dean, Faculty of Nursing

Office of Institutional Review Board Faculty of Nursing Mahidol University Room 503 Faculty of Nursing, Mahidol University 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170, THAILAND Tel: (662)-441-5333 Ext. 2531, 2532

Guideline for the research conduct post approval

The Institutional Review Board, Faculty of Nursing, Mahidol University

1. Use only documents with the stamp from the Institutional Review Board, Faculty of Nursing, Mahidol University (IRB-NS) for conducting the research (e.g., Instruments/ Questionnaires, Informational letter, Informed consent form)

2. If the investigator wishes to make any changes on the research protocol, the "Protocol Amendment Form" and all amended documents are required to submit to the IRB-NS for considerations before continuing the research.

3. If the serious adverse events or the suspected unexpected serious adverse events occur to the research participants, the "Adverse Event Report Form" is required to submit to the IRB-NS for considerations before continuing the research.

4. IF the research project is completed within 1 (one) year, the "Study Closure Form" is required to submit to the IRB-NS. If the project is needed to extend, the "Progress Report Form" is required to submit to the IRB-NS 1 (one) month in advance of the expiry date.

5. If the report for data collection is required, report as follows:

☑ Normal (Report at the renewal of the COA or at the project closure)

☐ Report at 25% of the data collection

☐ Report at 50% of the data collection

Date July 8, 2016

APPENDIX C
PARTICIPATION INFORMATION SHEET

(English version)

4 JUL 2016
29.0703RS1

PARTICIPANT INFORMATION SHEET I

In this document, there may be some statements that you do not understand. Please ask the principal investigator or his/her representative to give you explanations until they are well understood. To help your decision making in participating the research, you may bring this document home to read and consult your relatives, intimates, personal doctor or other doctor.

Title of Research Project: The effect of comfort program on satisfaction among patient receiving colonoscopy

Name of Researcher: Truong Thi Thuy Huong

Research Site-Office and its telephone number available for contact both in and out of the office hours:

Bach Mai Hospital: 78 Giai Phong Street, Dong Da District, Hanoi city, Viet Nam. Coode: 100000. Telephone number: (+84) 4 3869 3731 - Fax : (+84) 4 3869 1607

Source of Fund: No research funding

This research project aims to evaluate the effect of comfort program on satisfaction anxiety and pain among patients receiving colonoscopy, which expects the following benefits:

1. Providing basic data about effect of comfort program on satisfaction, anxiety and pain of patients receiving colonoscopy

2. In the future, developing program by using this data to improve patients' satisfaction of patient receiving colonoscopy.

However, in this study, the patient will not get directly benefit from intervention which research develop for them and endoscopy unit Bach Mai have the model for the other units. You are invited to participate in this research project because you are have been receiving colonoscopy and being 18 years old or above.

There will be 79 participants, and the research will last for 20- 30 minutes for answer questionnaires.

*To participate in this research is completely VOLUNTARY.

If you decide to participation the research project, you will go through the following procedure.

1) Researcher will organize private room to interview you or do questionnaires by yourself. Then, researcher uses three questionnaires for data collection. Questionnaires are:

1) Demographic data questionnaire 2) Hamilton Anxiety Rating Scale. 3) Numerical Rating Scale (NRS).

2) You will be performed colonoscopy with standard care including:

a) Nurses help you to register and wait for examination

b) Nurse guides you how to prepare bowel by verbally.

c) Nurses explain how to do the endoscopy, tell possible complication/accident for endoscopy and encourage you for prevent anxiety.

d) Nurses assist the doctor to take place the endoscopy. During the process, nurses guide you for positioning, directioning, and breathing.

e) Nurses help you to recover after endoscopy in recover room by assessing your conditions until you feel good. Finally, you will see the doctor before you leave the hospital.

3) After colonoscopy in the recovery room, the researcher will guide you for post endoscopy care at home and warning for complication and you fill out three questionnaires for data collection. Questionnaires are: 1) Hamilton Anxiety Rating Scale. 2) Numerical Rating Scale (NRS), 3) Modified GHAA-9 questionnaire.

4) During interviewing or doing questionnaire, you may feel discomfort. You can stop and rest for a while until you feel comfort to continue. You may have unexpected conditions for example pain or dyspnea; researcher will take care until you are stable. The researcher will continue for data collection except you refuse to continue. If you want to stop participation to this study, you can withdraw from the study at any time.

5) During colonoscopy, you might have perforation, blood pressure over 170/90 mmHg or under 90/60 mmHg, bleeding, or severe abdominal cramping, the physician will respond and take care. The researcher will stop data collection process and terminate the case.

If you do not participate in this research project, you will receive a standard assessment and treatment.

If you have any questions about this research project please feel free to contact Mrs Truong Thi Thuy Huong Telephone: (+84) 912614666

You don't get any money participating in this research.

If relevant information arises about benefits and risks of the research project, the researcher will inform the participant immediately and without concealment.

The participant's private information will be kept confidential, it will not be subject to an individual disclosure, but will be included in the research report as part of the overall results. Individual information may be examined by a researcher, the ethics committee, etc.

You have the right to withdraw from the project at anytime without prior notice. And the refusal to participate or the withdrawal from the research project will not at all affect the proper service or treatment that you will receive.

This research project is approved by The Institutional Reviews Boards, Faculty of Nursing (IRB-NS) at the office of IRB-NS room 503 5th floor, Faculty of Nursing, Mahidol University, 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170 Thailand Tel 0066 2 441 5333 ext 2531, 2532 Fax 0066 2 441 5333 ext 2531, Email: nsirbnursing@mahidol.ac.th.

Then submit document and the result to SMP- IRB institutional review board of Vietnam National University. The name of IRB Chair – SMP: Associate Professor Nguyen Thi Luyen MD-PhD. Address: Y1 Building, No.144 Xuan Thuy street, Cau Giay district, Ha Noi, Mobile phone number of IRB chair (+84) 913597423, telephone of SMP + 84 - 4 -37450188

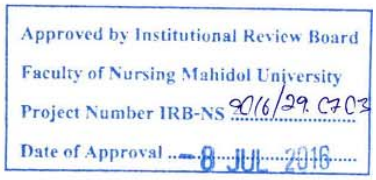
On the condition that I am not treated as indicated in the information sheet distributed to the subjects, I can contact the Chair, or the representative of the IRB-NS at the contact address presenting above.

I thoroughly read the details in this document.

Signature..... Participant

(.....)

Date.....



- 4 JUL 2016
29.0703RS1

PARTICIPANT INFORMATION SHEET II

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Title of Research Project: The effect of comfort program on satisfaction among patient receiving colonoscopy

Name of Researcher: Truong Thi Thuy Huong

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1. Providing basic data about effect of comfort program on satisfaction of patients receiving colonoscopy

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In this study, the patient will get directly benefit from intervention which research develop for them and endoscopy unit Bach Mai have the model for the other units. You are invited to participate in this research project because you are have been receiving colonoscopy and being 18 years old or above.

There will be 79 participants, and the research will last for 20- 30 minutes for answer questionnaires.

*To participate in this research is completely VOLUNTARY.

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1) Researcher will organize private room to interview you or do questionnaires by yourself. Then, researcher uses three questionnaires for data collection. Questionnaires are: 1)

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 2016/ 29.0703RS1
Date of Approval - 8 JUL 2016

Demographic data questionnaire 2) Hamilton Anxiety Rating Scale. 3) Visual Analog Scale (VAS)

2) The researcher will providing information guidelines include the information for bowel preparation and colonoscopy process by using posters and leaflets with short, diagramed form easy to understand. These posters and leaflets will be distributed to you directly, hanged on waiting room wall and toilet wall. Improving environment is planned to make change in area of colonoscopy room, waiting & reception room and toilets. For reducing pain, you will obtain repositioning and breathing guiding during colonoscopy. The analgesic drug may be applied when having doctor's indication. Researcher help you to recover after endoscopy in the recovery room by monitoring until you recover with stable vital signs. Finally, you will see the doctor before you leave the hospital.

3) After colonoscopy in the recovery room, the researcher will guide you for post endoscopy care at home and warning for complication according to the leaflet and you fill out three questionnaires for data collection. Questionnaires are: 1) Hamilton Anxiety Rating Scale. Numerical Rating Scale (NRS) 3) Modified GHAA-9 questionnaire.

4) During interviewing or doing questionnaire, you may feel discomfort. You can stop and rest for a while until you feel comfort to continue. You may have unexpected conditions for example pain or dyspnea; researcher will take care until you are stable. The researcher will continue for data collection except you refuse to continue. If you want to stop participation to this study, you can withdraw from the study at any time.

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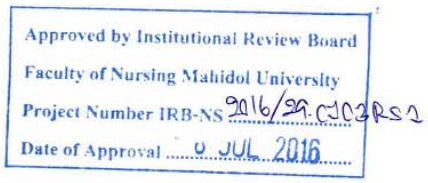
I thoroughly read the details in this document.

Signature..... Participant

(.....)

Date.....



(Vietnamese version)

THÔNG TIN DÀNH CHO ĐỐI TƯỢNG NGHIÊN CỨU

Tài liệu này sẽ có một số vấn đề Ông/bà có thể không hiểu. Hãy hỏi người nghiên cứu hoặc người đại diện của cô ấy để đưa cho Ông/Bà lời giải thích cho đến khi Ông/Bà hiểu rõ ràng vấn đề. Để giúp cho việc quyết định có tham gia vào chương trình nghiên cứu hay không, Ông/Bà có thể mang tài liệu này về nhà để đọc hoặc hỏi ý kiến người thân và các bác sĩ.

Tên đề tài nghiên cứu: Tạo sự thoải mái để làm tăng sự hài lòng của người bệnh nội soi đại tràng

Người thực hiện nghiên cứu: Trương Thị Thúy Hường

Địa chỉ và điện thoại liên hệ trong và ngoài giờ hành chính (Đại diện của người nghiên cứu): Bệnh viện Bạch Mai: 78 đường Giải Phóng, Quận Đống Đa, Hà Nội, Việt Nam. Mã bưu chính: 100000. Số điện thoại: (+84) 438683731 Fax: (+84). 438691607

Nguồn kinh phí: tự túc

Mục đích của nghiên cứu: nghiên cứu này nhằm tạo sự thoải mái để làm tăng mức độ hài lòng của người bệnh nội soi đại tràng, với các lợi ích được kì vọng, bao gồm:

1) Nghiên cứu này cung cấp dữ liệu cơ bản về tạo sự thoải mái để làm tăng mức độ hài lòng của người bệnh nội soi đại tràng
2) Trong tương lai, chương trình này tạo sự thoải mái để làm tăng mức độ hài lòng của người bệnh nội soi đại tràng

Tuy nhiên, trong nghiên cứu này, người tham gia nghiên cứu có thể không thu được các lợi ích trực tiếp, nhưng những người bệnh mắc bệnh phổi tắc nghẽn mạn tính sẽ thu được các lợi ích trong tương lai.

Ông/Bà được mời tham gia chương trình nghiên cứu này bởi vì Ông/Bà đã trên 18 tuổi và được chỉ định nội soi đại tràng.

Sẽ có khoảng 79 người tham gia và cuộc phỏng vấn sẽ kéo dài khoảng từ 20 – 30 phút.

Việc tham gia nghiên cứu này của Ông/Bà là hoàn toàn TỰ NGUYỆN.

Nếu Ông/Bà quyết định tham gia nghiên cứu này, Ông/Bà sẽ trải qua các bước sau:

1) Người nghiên cứu sẽ yêu cầu Ông/Bà ký tên vào bản chấp thuận tham gia nghiên cứu
2) Người nghiên cứu sẽ thu thập một số thông tin của Ông/Bà từ hồ sơ bệnh án.
3) Nghiên cứu viên sẽ chuẩn bị phòng riêng để phỏng vấn Ông/bà hoặc Ông/bà có thể tự trả lời các câu hỏi. Sau đó nghiên cứu viên sẽ sử dụng bộ câu hỏi bao gồm 4 phần: 1) thông tin chung với 13 câu hỏi. 2) Thang đánh giá đau. 3) Thang đánh giá sự lo âu của người bệnh theo Hamilton với 14 câu hỏi – 4) Thang đánh giá mức độ hài lòng của người bệnh GHAA 9 với 12 câu hỏi. Tổng số 40 câu hỏi và được hoàn thành trong khoảng 20 – 30 phút. Trong suốt quá trình trả lời câu hỏi, nếu có câu hỏi nào Ông/ Bà không hài lòng hoặc khó trả lời Ông/ Bà có thể không trả lời.

Trong quá trình phỏng vấn, nếu Ông/bà cảm thấy khó chịu, Ông/bà có thể yêu cầu dừng lại và nghỉ ngơi cho đến khi Ông/bà cảm thấy dễ chịu trở lại và có thể tiếp tục

phỏng vấn. Nếu Ông/bà không muốn tham gia nghiên cứu nữa, Ông/bà có thể rút khỏi nghiên cứu bất kỳ lúc nào.

Trong quá trình phỏng vấn, Ông/ Bà có thể gặp phải những tình huống không mong đợi do bệnh tật. Nghiên cứu viên sẽ dừng cuộc phỏng vấn và liên lạc với Bác sỹ điều trị cho Ông/ Bà ngay lập tức để chăm sóc Ông/ Bà. Nghiên cứu viên sẽ chăm sóc Ông/bà cho đến khi Ông/bà ổn định.

Nếu Ông/Bà không muốn tham gia vào nghiên cứu này, Ông/Bà vẫn được điều trị và chăm sóc theo đúng quy trình chuẩn của bệnh viện mà không có bất cứ trở ngại nào sau khi rút khỏi nghiên cứu.

Nếu Ông/Bà có bất cứ thắc mắc nào, vui lòng liên hệ người thực hiện nghiên cứu này là Bà Trương Thị Thúy Hường. Số điện thoại: 0912614666.

Ông/Bà không được nhận và cũng không phải trả bất cứ một khoản chi phí nào khi tham gia nghiên cứu này.

Nếu có thêm thông tin gì về các lợi ích và rủi ro của nghiên cứu, nghiên cứu viên sẽ thông báo cho Ông/Bà ngay lập tức.

Thông tin của Ông/Bà sẽ được bảo mật tuyệt đối và không được tiết lộ dưới dạng thông tin cá nhân, tuy nhiên nó sẽ được thể hiện trong báo cáo tổng thể như là kết quả của một đề tài nghiên cứu khoa học. Thông tin cá nhân của Ông/Bà sẽ được kiểm tra bởi người nghiên cứu và Hội đồng đạo đức trong nghiên cứu y sinh học.

Ông/Bà có quyền rút khỏi nghiên cứu bất cứ khi nào mà không cần thông báo trước. Việc Ông/Bà rút khỏi chương trình nghiên cứu sẽ không ảnh hưởng đến chất lượng dịch vụ y tế mà Ông/Bà thụ hưởng.

Đề tài nghiên cứu này được chấp thuận bởi Hội đồng Đạo đức trong nghiên cứu Y sinh học, Khoa Điều Dưỡng, Đại học Mahidol, tầng 5 phòng 504, số 999/4 đường Phuttamonthon 4, Salaya, Nakhon Pathom 73170 Thái Lan. Điện thoại 0066 2 441 5333 số máy lẻ 2531, 2532. Fax 0066 2 441 5333 số máy lẻ 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com.

Đề tài nghiên cứu này cũng được chấp thuận bởi Hội đồng Đạo đức trong nghiên cứu Y sinh học, Đại học Quốc gia Hà Nội, tòa nhà Y1, 144 đường Xuân Thủy, quận Cầu Giấy, thành phố Hà Nội, Việt Nam. Mã bưu chính: 100000, số điện thoại liên lạc: +84437450118, Fax: +84-4-37450146. Email: smp@vnu.edu.vn.

Nếu tôi không được hưởng sự điều trị như trong bản thông tin đưa ra, tôi có thể liên lạc với Hội đồng đạo đức, Khoa Điều dưỡng, Đại học Mahidol hoặc Hội đồng đạo đức trong nghiên cứu Y sinh học, Khoa Y dược, Đại học Quốc Gia Hà Nội với các thông tin liên lạc như đã nêu trên.

Tôi đã đọc kỹ và hiểu toàn bộ chi tiết nêu trong bản thông này.

Ngày.....

Họ tên, chữ ký người tham gia nghiên cứu

.....

APPENDIX D
INFORMED CONSENT

(English version)

- 4 JUL 2016
29-C7C3RS1

IRB-NS Form No. 4

Consent Form for Informed and Voluntary Participation in Research

Date...../...../.....

My name is....., aged.....years old,
Now living at the address: No.....Road/street.....
Sub-district/tambon.....District/amphur.....
Province.....Postal code.....Tel.No.....

I give my consent to participate as a subject in the research project entitled: the effect of comfort program on satisfaction, anxiety and pain among patient receiving colonoscopy.

In so doing, I am informed of the background and purpose of research project; its procedural details to carry out or to be carried out; its expected benefits and risks that may occur to the subjects, including methods to prevent and handle harmful consequences; and payment/ incentives, and expense. I thoroughly read the detailed statements in the information sheet given to the research subjects, I was also given explanations and my questions were answered by the head of the research project. I was explained that researcher will collect some demographic data from my medical record form. I was explained that during interview, use questionnaire, or receive colonoscopy if I feel uncomfortable. The researcher will stop the process until I feel comfort to continue or I can stop participation in the study.

I consent to participate as a subject in this research project.

On the condition that I have any questions about the research procedures, or on the condition that I suffer from an undesirable side effect from this research, I can contact Mrs. Truong Thi Thuy Huong via Telephone (+84) 912.614.666. or email: thuyhuong13573@gmail.com.

On the condition that I am not treated as indicated in the information sheet distributed to the subjects, I can contact the Chair, or the representative of the IRB-NS at the office of IRB-NS room 503 5th floor, Faculty of Nursing, Mahidol University, 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170 Thailand Tel 0066 2 441 5333 ext 2531, 2532 Fax 0066 2 441 5333 ext 2531, Email: nsirbnursing@mahidol.ac.th.

Version 5 date 10 August 2015

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 2016/29.C7C3RS1
Date of Approval 8 JUL 2016

IRB-NS Form No. 4

I am aware of my right to further information concerning benefits and risks from the participation in the research project and my right to withdraw or refrain from the participation anytime without any consequence on the service or health care I am to receive in the future, I consent to the researcher's use of my private information obtained in this research, but do not consent to an individual disclosure of private information. The information must be presented as part of the research results as a whole.

I thoroughly understand the statement in the information sheet for the research subjects and in this consent form. I thereby give my signature.

Signature……Participants/Proxy/

(……..)

Date……..……..……..

Signature……..Person in Charge of Informing and Requesting a Consent/Head of (Mrs. Truong Thi Thuy Huong) Research Project/Date……..…

In case that the participant is not literate, the reader of all the statements for the participant is (Mr./Mrs./Ms……), who gives his/her signature as a witness.

Signature……Witness

(……..)

Date……..……..

IRB-NS Form No. 4

- 4 JUL 2016
29.0703RS1

Consent Form for Informed and Voluntary Participation in Research

Date……/……/…….

My name is……., aged……...years old,
Now living at the address: No……..Road/street……
Sub-district/tambon……..District/amphur……..
Province……..Postal code……Tel.No……

I give my consent to participate as a subject in the research project entitled: the effect of comfort program on satisfaction, anxiety and pain among patient receiving colonoscopy.

In so doing, I am informed of the background and purpose of research project; its procedural details to carry out or to be carried out; its expected benefits and risks that may occur to the subjects, including methods to prevent and handle harmful consequences; and payment/ incentives, and expense. I thoroughly read the detailed statements in the information sheet given to the research subjects, I was also given explanations and my questions were answered by the head of the research project. I was explained that researcher will collect some demographic data from my medical record form. I was explained that during interview, use questionnaire, or receive colonoscopy if I feel uncomfortable. The researcher will stop the process until I feel comfort to continue or I can stop participation in the study.

I consent to participate as a subject in this research project.

On the condition that I have any questions about the research procedures, or on the condition that I suffer from an undesirable side effect from this research, I can contact Mrs. Truong Thi Thuy Huong via Telephone (+84) 912.614.666. or email: thuyhuong13573@gmail.com.

On the condition that I am not treated as indicated in the information sheet distributed to the subjects, I can contact the Chair, or the representative of the IRB-NS at the office of IRB-NS room 503 5th floor, Faculty of Nursing, Mahidol University, 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170 Thailand Tel 0066 2 441 5333 ext 2531, 2532 Fax 0066 2 441 5333 ext 2531, Email: nsirbnursing@mahidol.ac.th.

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 2016/29.0703RS1
Date of Approval - 8 JUL 2016

IRB-NS Form No. 4

I am aware of my right to further information concerning benefits and risks from the participation in the research project and my right to withdraw or refrain from the participation anytime without any consequence on the service or health care I am to receive in the future, I consent to the researcher's use of my private information obtained in this research, but do not consent to an individual disclosure of private information. The information must be presented as part of the research results as a whole.

I thoroughly understand the statement in the information sheet for the research subjects and in this consent form. I thereby give my signature.

Signature……Participants/Proxy/

(……..)

Date……..……..……..

Signature……..Person in Charge of Informing and Requesting a Consent/Head of (Mrs. Truong Thi Thuy Huong) Research Project/Date……..…

In case that the participant is not literate, the reader of all the statements for the participant is (Mr./Mrs./Ms……), who gives his/her signature as a witness.

Signature……Witness

(……..)

Date……..……..

INFORMED CONSENT (Vietnamese version)

BẢN CHẤP THUẬN THAM GIA NGHIÊN CỨU

Ngày...../...../.....

Tên tôi là ....., Tuổi: .....

Mã ID (Người nghiên cứu ghi):.....

Địa chỉ: .....

Mã vùng: ..... Số điện thoại: .....

Trước tiên, tôi xin bày tỏ sự đồng ý tham gia vào đề tài nghiên cứu có tên là: **Tạo sự thoải mái làm tăng mức độ hài lòng cho người bệnh nội soi đại tràng.**

Trước khi tham gia nghiên cứu tôi đã được thông báo về mục đích của nghiên cứu này, chi tiết quá trình thực hiện nghiên cứu, các lợi ích và rủi ro có thể xảy ra đối với người tham gia nghiên cứu, các biện pháp ngăn ngừa và giải quyết các tác dụng không mong muốn có thể xảy ra đối với người tham gia nghiên cứu, cả về chi phí tham gia nghiên cứu. Tôi đã đọc kỹ toàn bộ thông tin trong bản thông tin dành cho đối tượng nghiên cứu. Bên cạnh đó, các câu hỏi của tôi cũng được giải đáp bởi người thực hiện nghiên cứu.

Tôi đồng ý tham gia vào nghiên cứu này như một đối tượng nghiên cứu.

Trong trường hợp có bất cứ câu hỏi nào hoặc có vấn đề mới phát sinh trong quá trình nghiên cứu, tôi có thể liên hệ với chị Trương Thị Thúy Hường số điện thoại: 0912614666 email: thuyhuong13573@gmail.com (Số điện thoại liên lạc trên được kết nối 24/24 h).

Nếu tôi không được điều trị và chăm sóc như những điều khoản được đề cập trong bản thông tin dành cho đối tượng nghiên cứu, tôi có thể liên lạc với Hội đồng Đạo đức, Khoa Điều dưỡng, Đại học Mahidol, đặt văn phòng tại tầng 5 phòng 503 Đại học Mahidol, 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73.170 Thái Lan. Tel 00662441 5333 ext 2531, 2532 0066 Fax 24.415.333 ext 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com

Tôi cũng có thể liên lạc với Hội đồng đạo đức trong nghiên cứu Y sinh học, Khoa Y Dược, Đại học Quốc Gia Hà Nội. Địa chỉ: tòa nhà Y1, số 144 phố Xuân Thủy, quận Cầu Giấy, Hà Nội, Việt Nam; điện thoại: 04-37450188; fax: +84437450146; email: smp@vnu.edu.vn.

Tôi nhận thức được quyền của mình để tiếp tục nhận thông tin liên quan đến lợi ích và rủi ro từ việc tham gia vào các dự án nghiên cứu và tôi có quyền rút khỏi nghiên cứu hoặc từ chối không tiếp tục tham gia nghiên cứu bất cứ lúc nào mà không cần lý do, tôi bằng lòng để nghiên cứu viên sử dụng thông tin cá nhân cho việc nghien cứu, nhưng không đồng ý việc tiết lộ thông tin cá nhân. Các thông tin phải được trình bày như là một phần của kết quả nghiên cứu.

Tôi hoàn toàn hiểu được tuyên bố trong bản thông tin dành cho đối tượng nghiên cứu và trong phiếu chấp thuận tham gia nghiên cứu này. Sau đây là chữ ký của tôi.

Chủ nhiệm đề tài	**Người tham gia nghiên cứu**
(Ký và ghi rõ họ tên)	*(Ký và ghi rõ họ tên)*

APPENDIX E
INSTRUMENTS

(English version)

INSTRUMENT

Part 1 Patient's characteristic

There are 13 items that include general information and illness information among patients. With patient's general information, researcher collect data from medication recorded.

The following questions that related to your personal information. Please tick (√) or fill in blanks in the following questions:

Code Number: .....

1. Gender: ☐ Male ☐ Female
2. Age: ☐☐ Month ☐☐☐☐ Year
3. Weight (Kg): ..... Height (cm):..... BMI: .....
4. Marital status:
   - ☐ Married ☐ Single
   - ☐ Separated ☐ Divorced ☐ Widowed
5. Education level
   - ☐ Primary school ☐ Secondary school
   - ☐ High school ☐ Two years certificate
   - ☐ Bachelor ☐ Post graduated
6. Occupation
   - ☐ Famer ☐ House wife
   - ☐ Retired ☐ Staff government
   - ☐ Other: .....
7. Location of residence:
   - ☐ City
   - ☐ Rural
   - ☐ Mountain
8. Income personal/family: .....VND/USD
9. Payment method
   - ☐ Government ☐ Insurance
   - ☐ Self-pay ☐ Organization
10. How many people are living with you? .....
11. Diagnosis: .....
12. How many times have you ever colonoscopy? .....
13. Vital sight: Blood pressure: ...mmHg; Temperature: ....°C; Pulse:...../min; Breath:...../min

Part 2 Numerical Rating Scale (NRS)

I would like you to rate your pain on a scale from zero to ten. 'Zero' means you have no pain at all. 'Ten' means the worst possible pain you can image. What number would you give to your pain?

0	1	2	3	4	5	6	7	8	9	10

No pain **The worst possible pain**

Part 3 Hamilton Anxiety Rating Scale (HAM-A)

This scale includes 14 items that respond to describe certain feeling. The patient finds the best answer which refers patient's extent conditions.

Please use " ✓ " to indicate the best answer for each question.

0 = Not present 1 = Mild 2 = Moderate

3 = Severe 4 = Very severe.

No	Content	0 Not present	1 Mild	2 Moderate	3 Severe	4 Very severe
1	**Anxious mood** Worries, anticipation of the worst, fearful anticipation, irritability					
2	**Tension** Feelings of tension, fatigability, startle response, moved to tears easily, trembling, feelings of restlessness, inability to relax.					
3	**Fears** Of dark, of strangers, of being left alone, of animals, of traffic, of crowds.					
4	**Insomnia** Difficulty in falling asleep, broken sleep, unsatisfying sleep and fatigue on waking, dreams, nightmares, night terrors.					
5	**Intellectual** Difficulty in concentration, poor memory.					
6	**Depressed mood** Loss of interest, lack of pleasure in hobbies, depression, early waking, diurnal swing.					

No	Content	0 Not present	1 Mild	2 Moderate	3 Severe	4 Very severe
8	**Somatic (sensory)** Tinnitus, blurring of vision, hot and cold flushes, feelings of weakness, pricking sensation.					
9	**Cardiovascular symptoms** Tachycardia, palpitations, pain in chest, throbbing of vessels, fainting feelings, missing beat.					
10	**Respiratory symptoms** Pressure or constriction in chest, choking feelings, sighing, dyspnea.					
11	**Gastrointestinal symptoms** Difficulty in swallowing, wind abdominal pain, burning sensations, abdominal fullness, nausea, vomiting, borborygmi, looseness of bowels, loss of weight, constipation.					
12	**Genitourinary symptoms** Frequency of micturition, urgency of micturition, amenorrhea, menorrhagia, development of frigidity, premature ejaculation, loss of libido, impotence.					
13	**Autonomic symptoms** Dry mouth, flushing, pallor, tendency to sweat, giddiness, tension headache, raising of hair.					
14	**Behavior at interview** Fidgeting, restlessness or pacing, tremor of hands, furrowed brow, strained face, sighing or rapid respiration, facial pallor, swallowing, etc.					

Part 4 Modified GHAA- 9 Questionnaire

GHAA-9, the questionnaire measures level of satisfaction during colonoscopy has 12 items. In which, there are 10 items that measure satisfaction and 2 items that measure cleaning of colonl. How would you rate each of the question? Please use "✓" to indicate the best answer for each question.

No	Content	Excellent (5)	Very good (4)	Good (3)	Fair (2)	Poor (1)
1	How long you waited to get an appointment.					
2	Length of time spent waiting at the office for the procedure.					
3	The personal manner (courtesy, respect, sensitivity, friendliness) of the physician who performed your procedure.					
4	The technical skills (thoroughness, carefulness, competence) of the physician who performed your procedure.					
5	The personal manner (courtesy, respect, sensitivity, friendliness) of the nurses and the other support staff.					
6	Adequacy explaining of what was done for you (all your questions answer).					
7	Patients were provided information appropriately: about bow preparation prior colonoscopy, adverse or complication of colonoscopy (leaflet, poster).					
8	Environment of waiting room, examination room, toile are clean, comfortable and convenience.					
9	Overall rating of the visit					

10. If you have further examination demands, will you come back or recommend the hospital to others.

- ☐ Certainly never come back
- ☐ Not wishing to come back but lack alternatives
- ☐ Probably come back
- ☐ Certainly come back or recommend to others

11. Color of stools

☐ Dark and murky ☐ Brown and murky
☐ Dark orange ☐ Light orange ☐ Yellow

14. Assessment of physicians about Colon cleaning

☐ Excellent ☐ Good
☐ Acceptable ☐ A bit dirty ☐ Very dirty

.....

INSTRUMENTS (Vietnamese version)

BỘ CÂU HỎI NGHIÊN CỨU

Phần 1. Thông tin chung của người bệnh

Số thứ tự: ..... Mã bệnh án: .....

Mã ID:.....

Dưới đây là những câu hỏi sau liên quan đến thông tin cá nhân. Xin hãy đánh dấu tích (√) những câu hỏi sau

1. Giới: ☐ Nam ☐ Nữ
2. Tuổi ☐☐ Tháng ☐☐☐☐ Năm
3. Cân nặng.....kg Chiều cao ..... cm. BMI: .....
4. Tình trạng hôn nhân
   - ☐ Đã lập gia đình
   - ☐ Độc thân
   - ☐ Ly thân
   - ☐ Ly hôn
   - ☐ Góa (chồng hoặc vợ)
5. Trình độ học vấn
   - ☐ Tiểu học
   - ☐ Trung học cơ sở
   - ☐ Trung học phổ thông
   - ☐ Trung cấp/ chuyên nghiệp
   - ☐ Cao đẳng, Đại học
   - ☐ Sau đại học
6. Nghề nghiệp
   - ☐ Nông dân
   - ☐ Nội trợ
   - ☐ Nghỉ hưu
   - ☐ Nhân viên nhà nước
   - ☐ Khác: .....
7. Nơi ở
   - ☐ Thành thị
   - ☐ Nông thôn
   - ☐ Miền núi
8. Thu nhập của bản thân/ gia đình/tháng: .....VND/USD
9. Phương pháp chi trả viện phí
   - ☐ Chính phủ
   - ☐ Bảo hiểm
   - ☐ Tự chi trả
   - ☐ Tổ chức chi trả
10. Có bao nhiêu người sống cùng với bạn?

    .....
11. Chẩn đoán:

    .....
12. Đã nội soi bao nhiêu lần?.....
13. Dấu hiệu sinh tồn:

    Nhiệt độ:.....°C,Mạch:..../min, Nhịp tim:.. /min, Huyết áp:.....mmHg

Phần 2 Thang đo mức độ đau của người bệnh

Tôi muốn đánh giá sụ đau đớn của bạn bằng thang đo có số từ "không" đến "mười". Số "không" có nghĩa là không đau đớn, " Mười" có nghĩa là bạn rất đau, đau không thể chịu nổi. Số nào bạn chọn cho sự đau đớn của mình.

0	1	2	3	4	5	6	7	8	9	10

Không đau **Đau không thể chịu được**

Phần 3: Thang điểm đánh giá sự lo lắng (HAM-A)

Dưới đây là một danh sách các cụm từ mô tả cảm giác của mọi người trước, trong và sau khi soi đại tràng. Anh.chị hãy chọn câu trả lợi đúng nhất phù hợp với mức độ mà anh (chị) có.

Sử dụng dấu ✓ để chỉ ra câu trả lời đúng nhất

0 = Không 1 = Nhẹ 2 = Trung bình,
3 = Nặng, 4 = Rất nghiêm trọng

Stt	Nội dung	0	1	2	3	4
1	**Tâm trạng lo lắng** Những lo lắng, dự đoán về những điều tồi tệ nhất, về sự sợ hãi, khó chịu trong quá trình tiến hành nội soi					
2	**Căng thẳng** Cảm giác căng thẳng, mệt mỏi, giật mình, dễ rơi nước mắt, run rẩy, cảm giác bồn chồn, không thể thư giãn.					
3	**Cảm giác sợ hãi** Bóng tối, người lạ, bị bỏ lại một mình, động vật, giao thông, đám đông.					
4	**Mất ngủ** Khó ngủ, ngủ không yên giấc, hay gặp ác mộng, sợ bóng đêm.					
5	**Trí óc** Khó khăn trong việc tập trung, trí nhớ kém.					

6	**Tâm trạng chán nản** Mất quan tâm, thiếu niềm vui trong những sở thích, trầm cảm, thức dậy sớm.					
7	**Vấn đề thể chất** Đau nhức, co giật, cứng khớp, cơ run rẩy, nghiến răng, giọng nói run rẩy, tăng trương lực cơ bắp.					
Stt	**Nội dung**	**0**	**1**	**2**	**3**	**4**
9	**Triệu chứng tim mạch** Nhịp tim nhanh, đánh trống ngực, đau ngực, đau nhói của mạch máu, ngất cảm xúc, thiếu nhịp.					
10	**Triệu chứng hô hấp** Áp lực hoặc co thắt trong lồng ngực, nghẹn cảm xúc, thở dài, khó thở.					
11	**Triệu chứng tiêu hóa** Khó khăn trong việc nuốt, đau bụng thoáng qua, cảm giác nóng bụng, đầy bụng, buồn nôn, nôn mửa, sôi bụng, mất nhu động ruột, giảm cân, táo bón.					
12	**Triệu chứng tiết niệu** Tăng số lần đi tiểu					
13	**Phản xạ tự nhiên** Khô miệng, đỏ bừng, xanh xao, xu hướng đổ mồ hôi, chóng mặt, nhức đầu căng thẳng, dựng tóc gáy.					
14	**Hành vi tại các cuộc phỏng vấn** Sốt ruột, bồn chồn hoặc nhịp, run tay, long mày nhíu lại, khuôn mặt căng thẳng, thở dài hoặc hô hấp nhanh, xanh xao trên khuôn mặt, nuốt, vv					

Phần 4 Bộ câu hỏi khảo sát sự hài lòng của bệnh nhân nôi soi

Bộ câu hỏi này gồm 10 câu hỏi đánh giá mức độ hài lòng cuả bệnh nhân nội soi đại tràng và 2 câu hỏi đánh giá mức độ sạch của đại tràng. Với mỗi nội dung dưới đây, ông/ bà hãy làm ơn đánh giá mức độ hài lòng của mình. Sử dung dấu "✓" để chỉ ra câu trả lời cuả ông/ bà.

Stt	**Nội dung**	**Rất hài lòng** **(5)**	**Hài lòng** **(4)**	**Bình thường** **(3)**	**Không hài lòng** **(2)**	**Rất không hài lòng** **(1)**
1	Thời gian hẹn soi					
2	Thời gian chờ đợi để được soi					

Stt	Nội dung	Rất hài lòng (5)	Hài lòng (4)	Bình thường (3)	Không hài lòng (2)	Rất không hài lòng (1)
3	Phong cách cá nhân (lịch sự, tôn trọng, nhạycảm, than thiện) của các bác sĩ thực hiện thủ thuật					
4	Kỹ năng thực hiện thủ thuật của bác sỹ nội soi (kỹ lưỡng, cẩn thận và có năng lực)					
5	Phong cách cá nhân của kỹ thuật viên, nhân viên đón tiếp (tôn trọng, nhạy cảm, thân thiện)					
6	Bạn được giải thích thông tin đầy đủ về thủ thuật nội soi đại tràng					
7	Bạn được cung cấp thông tin đầy đủ về nội soi đại tràng (chuẩn bị, biến chứng có thể gặp) bằng các hình thức khác (tờ rơi, áp phíc)					
8	Phòng chờ, phòng soi, nhà vệ sinh thoải mái, thuật tiện					
9	Đánh giá chung về nội soi đại tràng (từ khi đón tiếp đến khi hoàn thành quy trình soi)					

10.Nếu Ông/Bà có nhu cầu soi lại thì bạn có lựa chọn như thế nào?

☐ Không bao giờ quay lại

☐ Không muốn quay lại trừ khi không còn sự lựa chọn nào khác

☐ Có thể sẽ quay lại

☐ Sẽ quay lại hoặc giới thiệu người khác đến soi

11. Màu sắc của phân

☐ Màu đen và tối màu ☐ Màu nâu và tối màu

☐ Màu cam đậm ☐ Màu cam nhạt ☐ Màu vàng

12. Đánh giá của bác sỹ nội soi về mức độ sạch của đại tràng

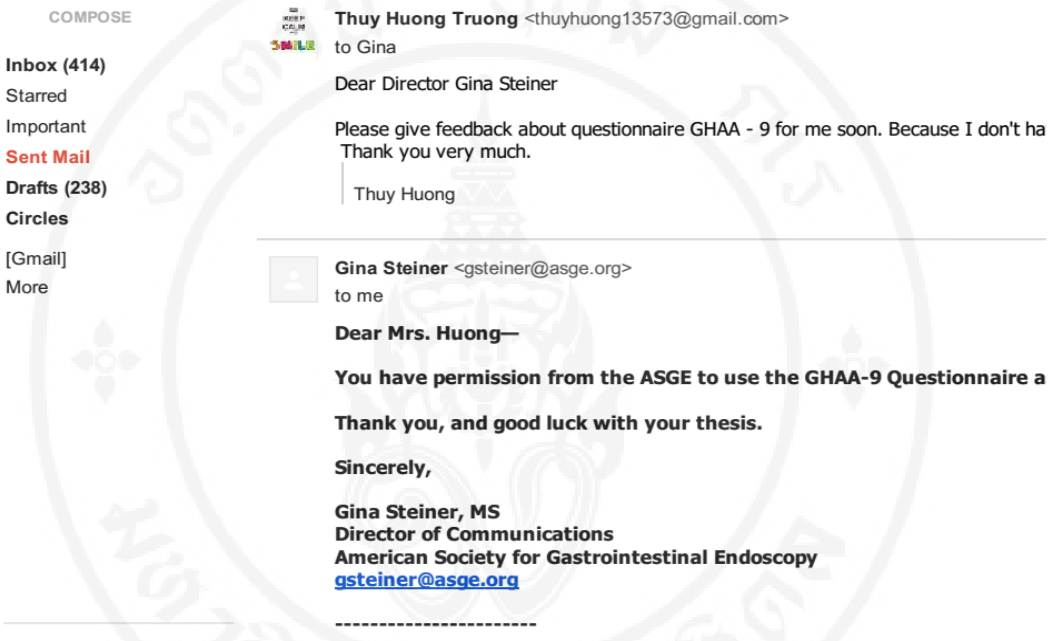
☐ Rất sạch ☐ Sạch

☐ Bình thường ☐ Bẩn một chút ☐ Rất bẩn

Góp ý của ông/ bà để dịch vụ soi đại tràng của chúng tôi được tốt hơn?

APPENDIX F

PERMISSION FOR USING INSTRUMENTS



COMPOSE

Inbox (414)
Starred
Important
Sent Mail
Drafts (238)
Circles
[Gmail]
More

Thuy Huong Truong <thuyhuong13573@gmail.com>
to Gina

Dear Director Gina Steiner

Please give feedback about questionnaire GHAA - 9 for me soon. Because I don't ha
Thank you very much.

Thuy Huong

Gina Steiner <gsteiner@asge.org>
to me

Dear Mrs. Huong—

You have permission from the ASGE to use the GHAA-9 Questionnaire a

Thank you, and good luck with your thesis.

Sincerely,

Gina Steiner, MS
Director of Communications
American Society for Gastrointestinal Endoscopy
gsteiner@asge.org

APPENDIX G
ADDITIONAL STATISTICAL ANALYSIS

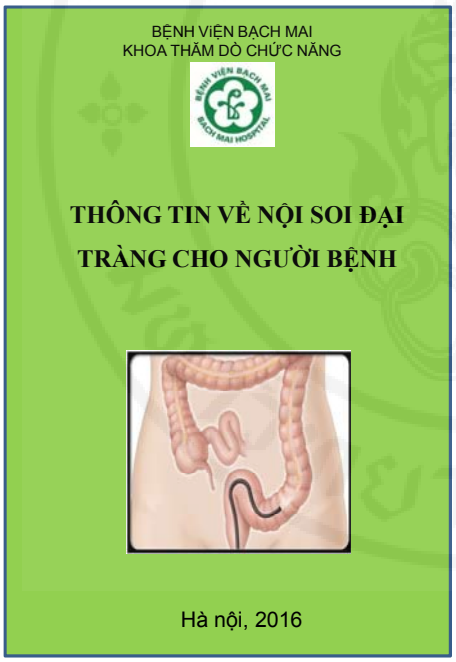
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Before_p2_pain	.149	158	.000	.960	158	.000
After_p2_pain	.120	158	.000	.966	158	.001
sHAM_after	.127	158	.000	.935	158	.000
sHAM_before	.145	158	.000	.943	158	.000
sum_Satisfaction	.227	158	.000	.842	158	.000

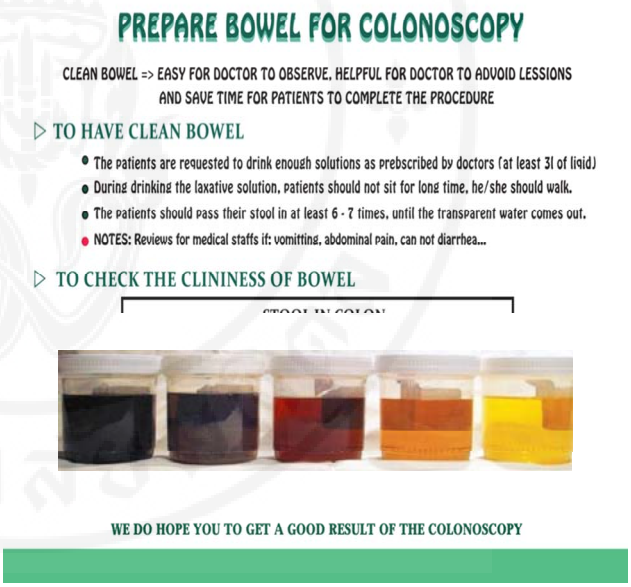
a. Lilliefors Significance Correction

APPENDIX H
THE GUIDING INFORMATION FOR COLONOSCOPY PATIENT

(ENGLISH VERSION)

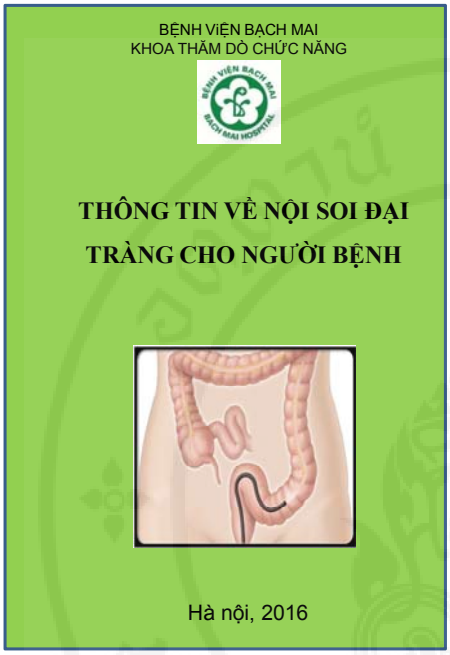
Booklet





(VIETNAMESEVERSION)

Sách hướng dẫn



QUY TRÌNH LÀM SẠCH ĐẠI TRÀNG TRƯỚC KHI SOI

CHUẨN BỊ LÀM SẠCH RUỘT TRƯỚC KHI NỘI SOI ĐẠI TRÀNG

ĐỂ LÀM SẠCH RUỘT:

- Người bệnh được yêu cầu uống đủ dịch theo đơn của bác sỹ (ít nhất 3 lít)

- Trong suốt quá trình uống thuốc nhuận tràng, người bệnh không nên ngồi lâu, nên đi bộ

- Người bệnh sẽ đi ngoài 7-8 lần cho đến khi thấy nước ra trong là được

-Thông báo cho nhân viên y tế nếu có dấu hiệu nôn, đau bụng, không đi ngoài được

-ĐỂ KIỂM TRA ĐỘ SẠCH CỦA RUỘT (Theo hướng dẫn của hình dưới dây)

APPENDIX I

THE GUIDING INFORMATION FOR COLONOSCOPY PATIENT (IN RESTROOM)

(ENGLISH VERSION)

Dark and murky	**Brown and murky**	**Dark orange and semi-clear**	**Light orange and mostly clear**	**Yellow and clear, like urine**
NOT OK	**NOT OK**	**NOT OK**	**Almost there**	**You're ready**

(VIETNAMESEVERSION)

Màu đen và tối màu	Màu nâu và tối màu	Màu cam đậm	Màu cam nhạt	Màu vàng
Chưa nội soi được	Chưa nội soi được	Chưa nội soi được	Nội soi được	Nội soi được

BIOGRAPHY

NAME	Truong Thi Thuy Huong
DATE OF BIRTH	May 13, 1973
PLACE OF BIRTH	Hanoi city, Vietnam
INSTITUTIONS ATTENDED	Hanoi Medical University, 2008-2011 Bachelor of Nursing Mahidol University, 2015-2016 Master of Nursing Science (Adult Nursing)
POSITION AND OFFICE	1997 – 2013: Nursing in Functional Examination Department, Bach Mai Hospital, Hanoi Vietnam 2014 – Present: Head nurse of Functional Examination Bach Mai Hospital, Hanoi Vietnam
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