Abstract of thesis entitled

An Evidence-based protocol of using videotaped information preparation in reducing anxiety level and promoting satisfaction in patients having colonoscopy

Submitted by

Cheung Ho Yee

For the degree of Master of Nursing

At the University of Hong Kong

in July 2016

Colonoscopy is an invasive procedure that allows endoscopists to examine the colon and terminal ileum with an endoscope for diagnostic and therapeutic purposes. Anxiety is commonly encountered in patients undergoing invasive medical procedures (Weinman et al., 1988). It is associated with a variety of undesirable outcomes such as higher consumption of sedatives, higher pain level, extended procedural time, increased risk of procedure-related complication, and refusal to co-operate with the endoscopic team (Hackett et al., 1998). From the literatures reviewed, providing relevant information to patients with an appropriate method can help to alleviate patients’ anxiety and to promote
satisfaction. Videotaped information is proven to be a good means to overcome the deficiency in written information.

In this dissertation, the literatures reviewed evidences on the effectiveness of videotaped information in reducing patients’ anxiety level and promoting patients’ satisfaction level are to be translated in order to formulate an evidence-based guideline. Implementation potential and evaluation plan in the target setting are assessed. A pilot study is formulated to assess the feasibility and transferability of the innovation, and to assess the quality and appropriateness of the assessment tools. A communication plan is to be established in order to facilitate a more comprehensive implementation plan.
An Evidence-based protocol of using videotaped information preparation in reducing anxiety level and promoting satisfaction in patients having colonoscopy

By

Cheung Ho Yee
R.N, B.N.

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Nursing at the University of Hong Kong

July 2016
Declaration

I declare that this dissertation represents my own work, and that it has not been previously included in a thesis, dissertation or report submitted to the University or to any other institute for a degree, diploma or other qualifications.

___________________
Cheung Ho Yee

July 2016
Acknowledgements

First of all, I would like to express my deepest sense of gratitude to my supervisor, Dr. William Li for his enlightenment, guidance and patience throughout the course of this thesis.

I am thankful to my classmates and colleagues for the help and support throughout the whole master studies.

Last but not least, I take this opportunity to express the profound gratitude from my deep heart to my beloved husband Dr. Terence Pun, sons, parents and siblings for their love and continuous support in my life journey.
# Table of Contents

Declaration .................................................................................................................... 4  
Acknowledgements .................................................................................................... 5  
List of Tables ................................................................................................................. 8  
List of Appendices ....................................................................................................... 9  
1.1 Background .......................................................................................................... 10  
1.2 Affirming the Need ............................................................................................. 11  
1.3 Objectives and Significance ............................................................................ 14  
   1.3.1 Objective ..................................................................................................................... 14  
   1.3.2 Significance ................................................................................................................ 15  
2.1 Search and Appraisal Strategies ................................................................... 16  
2.2 Results .................................................................................................................... 17  
2.3 Summary and Synthesis................................................................................... 21  
   2.3.1 Summary .................................................................................................................... 21  
   2.3.2 Synthesis ..................................................................................................................... 23  
   2.3.3 Conclusion.................................................................................................................. 25  
3.1 Transferability .................................................................................................... 27  
   3.1.1 Target setting and target population ............................................................... 27  
   3.1.2 Philosophy of Care .................................................................................................. 28  
   3.2.3 Participant Benefits .............................................................................................. 29  
3.2 Feasibility.............................................................................................................. 29  
   3.2.1 Setting Climate ......................................................................................................... 30  
   3.2.2 Manpower and workload ..................................................................................... 30  
   3.2.3 Resources and Support from other Department ......................................... 31  
   3.2.4 Evaluation tools and plan ..................................................................................... 32  
3.3 Cost-Benefit Ratio .............................................................................................. 33  
   3.3.1 Risks cause by the innovation ............................................................................ 33  
   3.3.2 Benefits from the innovation .............................................................................. 34  
   3.3.3 Material costs ......................................................................................................... 35  
3.4 Evidence-Based Practice Guideline ............................................................. 36  
4.1 Communication Plan ......................................................................................... 37  
   4.1.1 Identification of Stakeholders ............................................................................ 37  
   4.1.2 Communication Process and Strategies .......................................................... 38  
4.2 Pilot Study Plan ................................................................................................... 40  
   4.2.1 Objectives ................................................................................................................... 41  
   4.2.2 Time Frame ............................................................................................................... 41  
   4.2.3 Outcome measures and Data Collection ......................................................... 42  
   4.2.4 Refining the Guideline ........................................................................................... 42  
4.3 Evaluation Plan ................................................................................................... 43  
   4.3.1.1 Quantitative Evaluation ........................................................................................... 43  
   4.3.1.2 Qualitative Evaluation ........................................................................................... 44  
   4.3.2 Sample Size ........................................................................................................... 45  
   4.3.3 Timelines.................................................................................................................... 45  
   4.3.4 Basis for Implementation....................................................................................... 45
List of Tables

Table 1  Table of Evidence
Table 2  Table of Critical Appraisal
List of Appendices

Appendix 1 Colonoscopy information leaflet
Appendix 2 Critical appraisal checklist
Appendix 3 Level of evidence in terms of the study in Melnyk & Fineout-Overholt
Appendix 4 Material costs
Appendix 5 Evidence-based Practice Guideline on Pre-colonoscopy Information in Video format
Chapter 1
Introduction

1.1 Background

Colonoscopy is commonly performed for diagnostic and therapeutic purposes. It is an invasive procedure that allow endoscopist to evaluate the colon and terminal ileum with a colonoscope. Not only can the bowel be examined under direct vision for making diagnoses, biopsy sampling and therapeutic procedures can be carried out through the working portal. A colonoscope is a 1700 mm long, 12 mm wide flexible tube with a camera and a charge-coupled device at the distal end that enables high definition colored live imaging.

Although colonoscopy is a useful and versatile procedure, there are inherent risk and cost to such invasive procedure. Anxiety is commonly encountered in patients undergoing invasive medical procedures (Weinman et al., 1988). It is associated with various undesirable outcomes such as higher consumption of sedatives, higher pain level, extended procedural time, increased risk of procedure-related complications, and refusal to co-operate with the endoscopic team (Hackett et al., 1998). The anxiety induced by endoscopy is classified in four categories according to Drossman et al. (1996) and Maguire et al. (2004) including sensory discomfort like pain, fear of adverse examination finding, incompetence about the procedure and miscellaneous adverse perception such as fear of doctors. In the target setting, most patients expressed their worry and fear about the procedures by voicing out or indirectly reflected by abnormal
vital signs such as high blood pressure and tachycardia on arrival to the endoscopy centre.

According to Spielberger (1983), anxiety can be divided into two subcategories: state anxiety and trait anxiety. State anxiety is experienced periodically when an individual is stress, which is a transitory emotional state. It is altered from moment to moment. An example includes the anxiety provoked by an endoscopic procedure. Trait anxiety is a persisting level of anxiety that is not expected to vary from measurement to measurement. Several studies have shown that preparatory intervention can improve clinical outcome in patients undergo various types of endoscopies (Shipley, 1979; Agre, 1994).

1.2 Affirming the Need

Colorectal cancer is the commonest cancer and the second leading cause of cancer deaths in Hong Kong. According to the Department of Health (2015), it accounted for 16.5% of all cancer new cases in 2011, with 2534 male cases and 1916 female cases. Colorectal cancer develops predominantly from an adenomatous polyp although many colonic adenomas do not progress to cancer. A study on the natural history of colonic polyps suggested that it takes more than ten years for a polyp to dedifferentiate into a cancer (Winawer, 1999). The rate of cancer progression is affected by the size, villous history and severity of dysplasia in a polyp (Terry et al., 2002). The chance of developing into invasive cancer can be lowered by early identification and removal of colonic polyp. Brenner et al (2007) suggested that colonoscopy might reduce the risk of colorectal cancer. Pignone et al (2002) reported that the sensitivity and specificity of
endoscopic screening of colorectal cancer were >90% and 99% respectively. It is recommended by the Cancer Expert Working Group on Cancer Prevention and Screening under the Cancer Coordinating Committee of the Department of Health in Hong Kong that implementing a population-based colorectal cancer screening program is an important strategy in cancer prevention.

It is known that patients are less anxious if they are provided with pre-
procedure information concerning a diagnostic-therapeutic treatment (Ruffinengo C. et al., 2009). Although procedure related information is provided by endoscopists as a component of informed consent, patients may still have inadequate understanding of the procedure. The communication skill of individual endoscopies, amount of time allocated for detailed explanation, amount of information delivered are highly variable. Meanwhile, Stanley (1998) reported that the result is mixed with the use of leaflets to improve and standardize the information given. Many patients do not read or cannot fully understand the information provided on the leaflets. Electronic device such as videotape have the potential to overcome the deficiencies of information leaflets. Other than arranging sessions to deliver videotaped information, nurses are ready to answer patients’ enquiry in order to improve the confidence and patient satisfaction.

The target setting is one of the biggest public hospitals in Hong Kong, Patients are admitted for various endoscopic procedures. As in other public hospitals in Hong Kong, most colonoscopy appointments are made in out-patient clinic or in ward by gastrointestinal physician and colorectal surgeons in the target hospital, patients would not meet the endoscopist until they enter the procedural room.
Limited by the tight endoscopy schedule and tight working schedule of doctors, patients need to sign an informed consent form on the day of examination after a brief explanation by an intern doctor who has little experience with the procedure oneself. With plenty of questions and uncertainties in mind, inadequate time to digest the given information, patients go through the process with much anxiety. In the target hospital, written information in the form of leaflet (Appendix 1) is given to patients when an appointment is made by a clerk in the out-patient clinic or in ward. Such personnel is not specialized in endoscopy most of the time and they will not be able to explain to patients what they will come across and how they should perform to co-operate. Patients are instructed to read the leaflets and they can ask questions in the endoscopy centre. They are expected to know much about the procedure after reading the given leaflet thoroughly. Unfortunately, patients’ understanding is often over-estimated. In the present situation, there is no standardized guideline in giving pre-colonoscopy information to patients. The amount of information is given is provider dependent. As the workload in the endoscopy center is no lighter than in the ward, the problem of shortage of explanation time persists. A more effective, comprehensive and standardized way to provide information to patients is needed to ensure their understanding and co-operation. Pearson et al. (2005) suggested that videotaped information assure a standard level of teaching and overcome literacy problem.

Although literature supports that written information can effectively lower patients’ anxiety level (Kutluturkan et al., 2010; Morgan et al., 1998), videotaped information is believed to be a more effective means in delivering information than written information alone (Callaghan & Chan, 2001). The videotaped
information can be shown to all patients who are undergoing colonoscopy sitting in the waiting area over a television in the target hospital. There should have plenty of time for patients to watch and digest information from videotape before the colonoscopy, as patients are usually admitted to a day care centre a few hours before the colonoscopy for preparation. Other than setting up of intravenous access site, signing of consent form, preparatory time can be fully utilized in order to prepare patients for a smooth and uneventful colonoscopy with low anxiety and high tolerance with appropriate information given (Felley et al., 2008). Thus, chance of complications can be reduced and procedure time can be reduced (van Zuuren et al. 2006).

1.3 Objectives and Significance

1.3.1 Objective

1. To systematically review the current evidence in the effectiveness of using videotaped information preparation in reducing anxiety level in patients having colonoscopy.

2. To systematically review the current evidence in the effectiveness of using videotaped information preparation in promoting satisfaction in patients having colonoscopy.

3. To develop an evidence-based protocol in videotaped information preparation to patients in target hospital.

4. To determine the feasibility and transferability of implementing the protocol in target hospital.
1.3.2 Significance

Endoscopy generally triggers anxiety. Anxiety arises from a lack of knowledge about the procedure and fear of discomfort during the procedure (Clements & Melby, 1998; Jones et al, 2004; van Zuuren et al, 2006; Kutluturken et al, 2010). Anxiety may increase the chance of undesirable outcome like increase consumption of medications, increase pain experienced by patients, difficult for patients to cooperate during the procedure, lengthen of the procedural time and increase of complications (Hackett et al., 1998). It is stated that the compliance, successful rate of completing the endoscopy, pain level and patients’ satisfaction are increased if appropriate information is given to patients before the procedure is done (Abuksis et al, 2001; Kutluturkan et al., 2010). Videotaped information is proved to be a more useful form of information than written form alone (Hackett et al., 1998; Luck et al., 1999). Nowadays, providing education and preparatory information are part of advanced nursing care.

In the target hospital, it is not difficult to implement the videotape preparatory information before colonoscopy, as electronic devices and setting are already available.
Chapter 2
Critical Appraisal

2.1 Search and Appraisal Strategies

A systematic search of relevant studies is done in three electronic databases, Pubmed, CINAHL Plus and Cochrane library, from September to December 2015. Reference lists and related studies listed by the databases were screened as well. Keywords including colonoscopy, endoscopy, invasive procedure, surgery, video information, videotaped information and anxiety were used in the search. Title and abstract were screened first for the relevance. Full text was read carefully and screened by using the inclusion and exclusion criteria as below:

1. Inclusion criteria
   - In English
   - Target group of the study is aged above 16
   - Studies conduct after 1990
   - Meta-analysis, systematic review and controlled clinical trials
   - Include anxiety level of target group
   - Undergo colonoscopy, endoscopy or invasive procedure

2. Exclusion criteria
   - Target group below 16 years old
Critical appraisal tool developed by the Scottish Intercollegiate Guidelines Network (SIGN) shown in Appendix 2 was being used for appraising the quality of each selected studies as shown in Table 2. The SIGN was developed by the National Health Service (NHS) to provide evidence-based clinical practice guidelines that were derived from a systematic review of the scientific literature. The methodology checklist 2: randomized controlled trials was being used, as the five studies are all randomized controlled trials study. The quality of the studies was rated by completing ten questions in the checklist to assess how many criteria were fulfilled under the SIGN 50: A guideline developer’s handbook (Scottish Intercollegiate Guidelines Network, 2014). Results of the critical appraisal are shown in Table 2. Level of evidence (Appendix 3) of each study was assessed under the criteria suggested by Melnyk & Fineout-Overholt (2005) as shown in Table 1.

2.2 Results

As mentioned in Chapter 2.1, 1647 studies were being searched initially and 1610 studies were being excluded after reading the title or abstract. 32 studies were excluded as irrelevant after reading the full text under the inclusion and exclusion criteria. A PRISMA flowchart is attached as below (Figure 1). At last, 5 studies were chosen (Bytzer P. & Lindeberg B., 2007; Callaghan P. & Chan H.C., 2001; Gunay E. et al., 2015; Luck A. et al., 1999; Ruffinengo C., Versino E., Renga G., 2009).
All the five studies were randomized controlled trial studies conducted from 1999 to 2015 and all five studies had level II of evidence according to the criteria suggested by Melnyk & Fineout-Overholt (2005). Studies were conducted in Denmark (Bytzer P. & Lindeberg B., 2007), Hong Kong (Callaghan P. & Chan H.C., 2001), Turkey (Gunay E. et al., 2015), Australia (Luck A. et al., 1999) and Italy (Ruffinengo C., Versino E., Renga G., 2009). All the studies assigned subjects to treatment groups and control groups randomly. Sample sizes were ranged from 30 to 200. Two studies focused on patients undergoing colonoscopy (Bytzer P. & Lindeberg B., 2007; Luck A. et al., 1999), one focused on patients
undergoing gastroscopy (Callaghan P. & Chan H.C., 2001), one focused on patients undergoing bronchoscopy (Gunay E. et al., 2015) and the remaining one focused on patients undergoing coronaryography (Ruffinengo C., Versino E., Renga G., 2009). All studies had one study group and one control group. Among the studies, three studies were conducted with out-patients (Bytzer P. & Lindeberg B., 2007; Callaghan P. & Chan H.C., 2001; Luck A. et al., 1999) and two were conducted with in-patients (Luck A. et al., 1999; Ruffinengo C., Versino E., Renga G., 2009). All studies involved showing a five-to-ten minutes video to patients with information on the procedures in a separate room as intervention while four studies used written information for control group and the remaining one orientate patients with nursing staff as control (Ruffinengo C., Versino E., Renga G., 2009). Two studies focusing on colonoscopy (Bytzer P. & Lindeberg B., 2007; Luck A. et al., 1999) took 3-20 days for preparing the patients with informed consent and interventions while the remaining three studies started the study on the procedural day. All the five studies studied on patients’ anxiety level with the Spielberger State-Trait Anxiety Inventory (STAI) and one study (Callaghan P. & Chan H.C., 2001) used specifically the Chinese version on the target group. All studies showed a positive result in reducing State-Trait Anxiety Inventory score with the intervention. Three studies (Callaghan P. & Chan H.C., 2001; Gunay E. et al., 2015; Ruffinengo C., Versino E., Renga G., 2009) studied on patients’ satisfaction level and showed a positive result with increase in the satisfaction score.

According to SIGN 50: A guideline developer’s handbook (Scottish Intercollegiate Guidelines Network, 2014), the quality of the five studies rated from high quality to acceptable. Three studies (Gunay E. et al., 2015; Luck A. et
al., 1999; Ruffinengo C., Versino E., Renga G., 2009) was rated as high quality while the remaining ones were rated as acceptable (Bytzer P. & Lindeberg B., 2007; Callaghan P. & Chan H.C., 2001). All five studies stated clearly the focused question with PICO mentioned. All patients are randomized with adequate concealment method in all five studies. All study was a single center study. They randomized patients with numbered envelope randomly (Callaghan P. & Chan H.C., 2001), with thorough shuffled marked cards into sequentially numbered (Luck A. et al., 1999) and with a random number generator (Ruffinengo C., Versino E., Renga G., 2009). The remaining two studies did not mention about the randomization method. Only two studies (Bytzer P. & Lindeberg B., 2007; Gunay E. et al., 2015) mentioned that the investigators and the subjects were blinded to the study but it was not mentioned in the other studies. The characteristics of patients in intervention groups and control groups were similar and only the intervention was different between the groups. The Spielberger STAI was used as the tool for assessing anxiety level among the five studies. It is a reliable tool that is validated and being widely used. One of the studies (Callaghan P. & Chan H.C., 2001) used the Chinese State-Trait Anxiety Inventory for assessing Chinese subjects. The study outcomes of all five studies were analyzed by using various statistical methods. The drop out rate from 19% to 22.5% in two studies (Bytzer P. & Lindeberg B., 2007; Ruffinengo C., Versino E., Renga G., 2009) was mainly due to missing data and procedure abundance, thus intention to treat analysis could not be fulfilled among the three studies.
2.3 Summary and Synthesis

2.3.1 Summary

The aim of all five randomized controlled studies is to investigate the impact of videotaped information on patients’ anxiety level undergoing colonoscopies or invasive procedures. All studies reviewed are randomized control trial studies. All studies used the Spielberger State-Trait Anxiety Inventory to assess patients’ anxiety level. One study used the Chinese version of State-Trait Anxiety Inventory (Callaghan P. & Chan H.C., 2001). The State-Trait Anxiety Inventory is a well-validated and widely used self-report questionnaire assessing both state and trait anxiety. All studies mainly focused on the state anxiety and all studies showed an improvement in reducing the State-Trait Anxiety Inventory score in the intervention group. Therefore, STAI-State should be used in this study in order to assess patients’ anxiety level. It can help proving that the innovation is useful if reducing of STAI-State score is shown in this study.

Three of the five studies examined patients’ satisfaction level. Callaghan P. & Chan H.C. (2001) used a patients’ satisfaction questionnaire (PSQ) that was validated by a panel of senior medical and nursing staff; Gunay E. et al. (2015) used a Liekert scale from 0-5 point to identify patients’ satisfaction level; and Ruffinengo C., Versino E., Renga G. (2009) used a visual analogue scales. Two studies (Callaghan P. & Chan H.C., 2001; Ruffinengo C., Versino E., Renga G., 2009) carried out a pilot study as a trial in order to test the informative instrument, the measuring instrument and sample size. A well-designed patients’ satisfaction questionnaire should be designed for this study according to the local setting. The patients’ satisfaction questionnaire should be validated by experienced

21
endoscopists and endoscopy nurses in the target setting. A pilot study should be implemented in order to assess the quality and appropriateness of the patients’ satisfaction questionnaire.

It is mentioned that sex and previous experience would affect the anxiety scores since female’s general anxiety level is higher than male’s. In this study, randomization should be done properly in order to get rid of any deviation in result due to this factor. It is mentioned in several studies that patients’ anxiety level reduces and satisfaction level increases with better knowledge about the procedure. Therefore, information to be included in the video should be selected carefully according to the literatures reviewed. In all the studies, it is believed that the intervention is effective in increasing patients’ knowledge and understanding about the procedure and thus improving the anxiety and satisfaction level. In one study (Callaghan P. & Chan H.C., 2001), it suggested that the anxiety level is not as significant as expected secondary to Chinese people’s characteristic of not asking question and not exposing personal weakness to others. Therefore, they cannot obtain and understand the information that should be given to them. In this study, a well designed videotaped information should be designed in order to allow all candidates to understand the information provided and the candidates should be encouraged to seek help and ask questions individually if needed.

It is proved by the five studies that videotaped information is effective in reducing patients’ anxiety level and satisfaction level. Besides, all the studies stated that the results are coherent with past studies and literature reviewed. Videotaped information has the benefit to minimizing variation in communication abilities by different information providers and maximizing knowledge to patients.
Videotaped information can overcome the deficiencies of verbal or written information alone.

### 2.3.2 Synthesis

Three studies (Bytzer P. & Lindeberg B., 2007; Luck A. et al., 1999; Ruffinengo C., Versino E., Renga G., 2009) mentioned that the State-Trait Anxiety Inventory questionnaire should be done immediately before the procedure. Meanwhile, four studies (Callaghan P. & Chan H.C., 2001; Gunay E. et al., 2015; Luck A. et al., 1999; Ruffinengo C., Versino E., Renga G., 2009) measured the STAI-State level only since it is used to measure individual’s situational anxiety level. In this study, we should adopt that the STAI-State questionnaire to be used for assessing patients’ anxiety level on the same day before the procedure is done. It is also suggested that the satisfaction level should be done on the same day after receiving the videotaped information and reversal of sedation (Bytzer P. & Lindeberg B., 2007; Ruffinengo C., Versino E., Renga G., 2009). In this study, we should adopt to assess patients’ satisfaction level the same day after patients reverse from sedation.

It is suggested that many patients do not read the given written information or cannot fully understand the information. Videotaped information is a good alternative modality in overcoming this deficiency (Gunay E. et al., 2015). All studies implemented a five-to-ten minutes video that explains about the indication, risk and benefit, technical aspect of the procedure. Two of them (Callaghan P. & Chan H.C., 2001; Ruffinengo C., Versino E., Renga G., 2009) included the behavioral information about how patients should behave to
minimize discomfort while one (Ruffinengo C., Versino E., Renga G., 2009) mentioned sensory information about how patients would feel during and after the procedure. It was reported that mentioning risks and complications in the videotaped information may contribute to increase patient’s anxiety level (Bytzer P. & Lindeberg B., 2007; Luck A. et al., 1999), therefore information on risks and complication should be excluded as the purpose in this study is to reduce the anxiety level. Callaghan P. & Chan H.C. (2001) pointed out that the videotaped information should be shown to patients on the same day of the procedure was done in order to have better understanding and digestion of the information in order to reduce anxiety level. Besides, Callaghan P. & Chan H.C. (2001) also suggested that patients did not have enough time to digest the information received if patients watch the information once only, therefore repeating the same videotaped information in the waiting area should be implemented.

Though the sample size among the five studies was not big, from 30 to 200, three studies justified the targeted sample size. Callaghan P. & Chan H.C. (2001) mentioned that sample size of 30 is sufficient for a medium size to detect the differences between psycho-educational interventions; Bytzer P. & Lindeberg B. (2007) mentioned that sample size of 150 is sufficient for detecting clinical importance and significant difference of 10 points in the STAI scale; and Ruffinengo C., Versino E., Renga G. (2009) estimated from its pilot study that a sample size of 64 is good enough with a power of 0.80 and a significance of 95%.
2.3.3 Conclusion

The target hospital can use videotaped information in order to improve the service by reducing patients’ anxiety level, increasing satisfaction level and improving patients’ knowledge on colonoscopy. If the video is shown right before the procedure, there maybe insufficient time for patients to digest the information and ask questions. Therefore, it is recommended that the target hospital should allow adequate time for patients to watch the video and understand the content. The video can be looped repeatedly in the waiting area. Patients are encouraged to seek advice when necessary. Moreover, the content includes in the videotape information is also important. It is suggested that appropriate information being taught can help yielding a better outcome. Patients’ satisfaction questionnaire should be created by the target hospital and internal validation should be done in order to obtain a reliable result that is focused on the target group. A pilot study should be implement in order to test the tools, test for the feasibility of the innovation and calculate the sample size of its own. The target hospital can use the validated and high reliable STAI-State score to assess patients’ anxiety level as in all the five reviewed studies. Chinese STAI-State questionnaires can be considered to fit the target group.

To conclude, a videotaped information with appropriate content like indication, procedural information, sensory information, behavioral information, risk and benefit and possible findings is necessary in order to reduce patients’ anxiety level and to improve patients’ satisfaction level in target hospital. It is suggested that all the elements mentioned above should be considered in
implementing the protocol for patients undergo colonoscopy in order to achieve the best outcome with minimal cost.
Chapter 3
Implementation Potential and Clinical Guideline

In the previous chapters, background and the need of the innovation, objectives and significance are being discussed. Literature search and appraisal strategies are introduced. Summary and synthesis from the five selected studies are reviewed. In this chapter, the implementation potential and clinical guideline of the innovation will be discussed in following aspects: transferability of literatures reviewed, feasibility of innovation and cost-benefit ratio.

3.1 Transferability

3.1.1 Target setting and target population

The target setting is one of the endoscopy centres of the Hospital Authority in Hong Kong. There was around 20,000 cases performed in this endoscopy centre including around 3300 colonoscopy in the year 2015. The target group is patients who are undergoing elective colonoscopy in this centre.

All five studies were conducted in hospital; three of them were conducted in an endoscopy centre (Bytzer P. & Lindeberg B., 2007; Luck A. et al., 1999; Callaghan P. & Chan H.C., 2001) and two of them were conducted in in-patient setting for minimal invasive procedure which were bronchoscopy and coronarography (Gunay E. et al., 2015; Ruffinengo C., Versino E., Renga G., 2009). Since we are focusing on the effect of videotaped information preparation
in reducing anxiety level and promoting satisfaction in patients and all studies were conducted in hospital based, the innovation is considered to fit the proposed setting.

All subjects recruited among studies were adults and all of them were undergoing elective endoscopic or invasive procedures rather than emergency. Although there is only one study focusing on Chinese population in Hong Kong (Callaghan P. & Chan H.C., 2001) while others focusing on other cultural groups in foreign countries, anxiety level is believed to be similar among different cultural groups. Meanwhile, the Spielberger State-Trait Anxiety Inventory was implemented in all five studies to evaluate the anxiety level of patients. Therefore, the studies are considered to be transferrable to the target setting.

3.1.2 Philosophy of Care

According to the Hospital Authority, high quality patient-centered care is always the first priority in the core value. Thus, reducing patient’s anxiety level and increasing patient’s satisfaction with the innovation is always right in the philosophy of care of the Hospital Authority. In addition, it is mentioned in the Hospital Authority Strategic Plan 2012-2017 that improving patient and staff safety and improving service efficiency in a cost-effective way is one of the goals. As suggested by the published studies, by implementing the innovation, patients’ anxiety level will likely be reduced; patients’ satisfaction level will improve; usage of sedation will be decreased; and complication rate should reduce with a relatively low cost.
3.2.3 Participant Benefits

The innovation will be beneficial to quite a large number of patients in the target setting. According to the plan of the expending service, there will be at least 80 elective colonoscopies a week in the year 2016, which means that there will be approximately 4160 patients can be benefit from the innovation in the target setting.

It does not take long before the innovation can be implemented all the hardware are ready for use. A proper video has to be created. Evaluation tools like the Spielberger State-Trait Anxiety Inventory and patient satisfaction questionnaire are already ready to be used.

In conclude, the innovation is consider to be transferable in the aspects of target population, target setting, philosophy of care, beneficial to patients and length of implementation and evaluation.

3.2 Feasibility

After evaluating the implementation plan of the innovation, it is considered that there is no potential barrier since the innovation costs little but benefits much. The essential factors for this innovation will be discuss in the following part.
3.2.1 Setting Climate

For implementing any innovation, it requires support from administrators and organization. As mentioned in chapter 3.1, the purposes of the innovation match the philosophy of care of the Hospital Authority and it should be support by the organization. In addition, the General Nursing Manager and the Department Operation Manager of the target setting welcome and support all the evidence-based practice. Nurses are given enough freedom to carry out any new innovation that is reasonable, cost-effective, improves clinical service and promotes patient safety. On the other hands, since nurses have the autonomy to implement and evaluate new innovation, they have the freedom to terminate any innovation that is considered as undesirable.

3.2.2 Manpower and workload

To reach a consensus between administrator and staff, two main concerns are addressed. Administrators and organization concern about cost effectiveness. Nursing staffs concern about workload. The innovation aims to providing appropriate and standardized precolonoscopy information to patients who are undergoing colonoscopy with a set of videotaped information. Therefore, it will not interfere with the manpower and will not increase the workload of the target setting after the innovation is launched. On the contrary, it may help to save manpower and time on explaining to every single patient about the procedure. Therefore, nurses should be able to co-operate since the innovation is beneficial to patients and will not introduce extra workload. In the administrators level,
consensus should be able to reach also as it will only need to spend an affordable cost to improve the service and promote patients’ wellness. In return, the reputation of the organization can be increase and the health of the general public can be improved. In addition, many staff expressed that there is no policy and guidelines in the current setting to assess and minimize patients’ anxiety level besides some informal explanation by individual staff. Therefore, staff in the target setting will be ready and accepting the new innovation.

As mentioned, it does not require extra manpower and would not increase workload for staff when the innovation is launched, yet extra workload is needed for the committee members. Since the target setting already has information in written format and most of the committee members are specialized endoscopy nurse, necessary information is ready and no extra time is required to search for information. Staff will need to spend a day to record the information DVD and spend one more day to edit the DVD, there would not be too much extra workload for the committee members, they would probably welcome this innovation.

3.2.3 Resources and Support from other Department

Although most of the resources like television, computer and waiting area are available in the target setting, support from other departments is needed for this innovation. Once the innovation is approved, it needs support from the Information Technology Department for recording the videotaped information in DVD format and the Facility Management Department to provide some more chairs and to re-arrange the furniture in the waiting area. As the target hospital is one of the biggest hospitals under the Hospital Authority and it collaborates with
one of the universities in Hong Kong, there were over a hundreds of innovations launched here and most of the innovations involved multimedia. Therefore, the Information Technology Department in the target hospital is willing and able to collaborate as it has much experience on developing information by recording a DVD. From past experience, the Facility Management Department is very efficient to help managing any damaged equipment or help re-arranging any venue for different purpose in the target setting.

3.2.4 Evaluation tools and plan

A working group will be set up in order to facilitate the evaluation and implementation of the innovation. A patient satisfaction questionnaire is created by the committee members to measure patient’s satisfaction level and it is validated by one patient, one nursing specialist and the Chief Endoscopist. The patient satisfaction questionnaire consists of a set of questions that measures the adequacy, relevancy, understanding, and use of information provided to help patients cope with the colonoscopy. Each item scored 1 to 5, representing ‘strongly disagree’ to ‘strongly agree’ accordingly. A high score indicates a high level of satisfaction while a low score indicates a low level of satisfaction. Since the patient satisfaction questionnaire is created by the committee, no cost is needed. If patients report a higher score after watching the videotaped information indicates that the new innovation is clinically effective.

Patient’s anxiety level is measured by the Spielberger State-Trait Anxiety Inventory as suggested by the five studies. A low score indicates a lower anxiety level while a high score indicates a higher anxiety level. The STAI is available
from the internet and it is free to be download. If patients report a lower score after watching the videotaped information reflects that the new innovation is considered to be clinically effective.

### 3.3 Cost-Benefit Ratio

Before implementing any new innovation, the cost-benefit ratio should be evaluated besides considering the feasibility and transferability. We can consider in aspects like risk and benefit to patients, staff and organization. Besides, the cost of each item should be considered also.

In the present situation, the anxiety level and satisfaction level have never been evaluated and addressed. Thus, no guideline is implemented to solve the problem. It means that extra manpower, extra medical expenses, hospitalization cost and extra cost of sedation will be continued as a result of repeating procedure and adverse result from colonoscopy.

#### 3.3.1 Risks cause by the innovation

The use of videotaped information for colonoscopy would not cause any risk to patients in the target setting as the information is standardized and every patient is watching the same set of videotaped information. Moreover, there would not have any side effect, as the innovation is not an invasive procedure.
3.3.2 Benefits from the innovation

According to the literatures, it is proven that videotaped information can effectively reduced patients’ anxiety level (Kutluturkan et al., 2010; Morgan et al., 1998). Therefore, chance of complications can be reduced and procedure time can also be reduced (van Zuuren et al. 2006). If one perforation case can be reduced in each quarter, an estimated medical cost of around $100,000 including costs of manpower and materials of the surgery can be reduced. Thus, around $400,000 can be saved yearly. Moreover, patients are co-operating better when they understand more about the procedure, thus chance of repeating colonoscopy resulting from not co-operative patients can be minimized and use of extra sedation can also be reduced (Felly et al., 2008). According to the information of the target setting, the estimated medical cost of a colonoscopy is around $6,000 including costs of manpower and materials. Thus, at least $1,248,000 can be saved yearly if we can prevent at least one unsuccessful case in each day. In addition, cost of sedation can be reduced by at least $2,496 yearly if at least one case that requires extra sedation can be reduced daily. In the target setting, intravenous Pethidine 50mg/ml/Amp and Diazemuls 10mg/2ml/Amp are being use and cost $2/Ampoule and $10/Ampoule respectively. Therefore, the new innovation can help reducing much of the hospital cost for the organization.

Since patients are going to watch the videotaped information in the waiting area while they are waiting for the preparation and procedure, manpower can be reduced to make explanation to every single patient, therefore manpower can be spared to other parts in the target setting. With enough manpower for
procedure, the quality of care should be able to improve and thus the reputation of
the target setting will be higher.

Last but not least, the new innovation can increase nurses’ job satisfaction
since the overall quality of care can be increased, patients are more satisfied under
their care, reputation of the target setting is higher and the new innovation by
nurses is important in the organization. Besides, nurses are able to standardize
their knowledge with up-to-date information that can help to improve the quality
of care. It can also help to retain nursing manpower by increasing their job
satisfaction and providing chance for them to develop their professional.

3.3.3 Material costs

Besides calculating the cost that can be saved, material cost should be
analyzed. See the Appendix 4.

After analyzed, the manpower cost is $49,664; the equipment cost for
running the new innovation is $1,010; the consumable Cost for running the new
practice yearly is $9,360; and the evaluation Cost yearly is $8,320.

The total cost for implementing then new innovation in first year (HK
Dollars) = $49,664 + $1,010 + $9,360 + $8,320 = $68,354.

In conclude, the new innovation is a, evidence-based practice that is able
to satisfy different needs of patients, staff and the organization and meanwhile
promoting high quality of care with relatively low material cost. Therefore the
new innovation is worth to be implemented as the benefits outweigh the risk and
cost.
3.4 Evidence-Based Practice Guideline

After evaluating the implementation potential of providing precolonoscopy videotaped information to patients who are undergoing colonoscopy in order to relieve their anxiety level and increase their satisfaction towards the procedure, an evidence-based practice guideline on precolonoscopy preparation information in video format was established. The guideline is attached in Appendix 5.

The guideline is developed with reference of five selected studies. The level of evidence of each study and the grade of each recommendation are evaluated by referring to the Scottish Intercollegiate Guidelines Network (SIGN). A level of 1++ to 4 is assigned to level of evidence and a grade of A, B, C or D is assigned to grade of recommendation according to the “SIGN 50: A guideline develop’s handbook Annex B: Key to grades of recommandations” (Scottish Intercollegiate Guidelines Network, 2014). Two studied were graded 1+ (Bytzer P. & Lindeberg B., 2007; Callaghan P. & Chan H.C., 2001) while the other three studies graded 1++ (Gunay E. et al., 2015; Luck A. et al., 1999; Ruffinengo C., Versino E., Renga G., 2009). The evidence-based guideline was established based on the recommendations.

The guideline targets all the nurses in the target endoscopy centre.
Chapter 4
Implementation Plan

In chapter 3, the evidence-based practice guideline was developed and the implementation potential of the innovation was considered through evaluating the transferability, feasibility of the literature reviewed and cost-benefit ratio in the target setting. In this chapter, the implementation plan is developed through implementing the communication plan, pilot study plan and evaluation plan.

4.1 Communication Plan

4.1.1 Identification of Stakeholders

Stakeholders are the people who involves in the implementation of the innovation to facilitate the change and to carry out the innovation. Therefore, identifying the stakeholders is the key to success for implementing the new innovation, as they are the group of people who may have impact on the innovation.

In the first step of all the new innovations, gaining approval and support from the administrative and managerial levels is important. Otherwise, the innovation cannot be launched. Therefore, the Department Operation Manager (DOM), the Chief of Service (COS) of the Department, the Chief Endoscopist, the Ward Manager and the Advanced Practice Nurses (APN) are involved from the
beginning. Besides, all the endoscopists and endoscopy nurses are the stakeholders in the operation level.

4.1.2 Communication Process and Strategies

To have a successful implementation plan, communication among stakeholders and parties involved is essential in order to optimize the outcomes of the innovation and minimize risks associated with their non-support. A working group will be formed according to the innovation and tasks will be completed according to the time frame set as below. A six-month time frame is being fixed from proposing to implement the innovation.

In the first month of the implementation period, the investigator will discuss with the ward manager of the target setting on the idea of the new innovation. The literatures reviewed, proposal and relevant evidence will be presented to her. After getting ward manager's support and approval, the DOM and COS of the target setting will be contacted by her in order to obtain the approval from the department and hospital. Meanwhile, endoscopists and APNs of the target setting will be consulted for their professional opinions on the new innovation, the guideline and the tools that to be used i.e. the patient satisfaction questionnaires and Spielberger State-Trait Anxiety Inventory.

In the second month, a working group focuses on the innovation will be established in order to facilitate the implementation and facilitate communication among different parties. The composition of the working group includes the investigator, the Chief Endoscopist, an APN and two endoscopy nurses. The Chief Endoscopist acts as the medical advisor of the group, providing professional
information and identify potential risks and problems; the APN acts as the advisor in nursing aspect, she is responsible for identifying potential problems to implement the innovation among staff and identify potential problems that may be aroused by patients; the investigator acts as a bridge among all parties in order to have a better communication between the administrative and managerial level with the operation level. Furthermore, the investigator is responsible for briefing and educating nursing staff that will implement the innovation. There are two endoscopy nurses, one got her specialty over ten years and one got hers under five years. They are responsible for identifying problems that may be encountered when the innovation is put into practice and helping to expressing their feeling and concern towards the innovation after it is launched in different levels.

In the third month, a more detail proposal will be developed by the working group, which include the content of the DVD, a more accurate time frame of the implementation, the amount of the resources and materials needed, the arrangement of training session, the guideline of the innovation and evaluation plan. The proposal will then be submitted to the administrative level for granting final approval.

In the fourth month, the precolonoscopy videotaped information DVD will be recorded. The investigator is the coordinator for the recording process. The facility management unit and the information technology unit are involved. The two endoscopy nurses in the working group are the host of the video. The recording and editing process will be completed in this month.

In the fifth month, a one-hour training session will be provided to the endoscopy nurses in the conference room of the target setting. It is a compulsory training session to endoscopy nurses in the target setting while endoscopists are
welcome to participate since endoscopy nurses are the main implementers of the innovation while endoscopists can understand more on the preparation of their patients. There will be three identical sessions for staff to participate in order to match their shifted duty. The aims of the training session are to provide background information to staff, to explain the purpose and significance, to emphasize the nursing role and responsibility, to educate the implementers the proper way to carry out the innovation, to ensure compliance among staff to the guideline and to introduce the evaluation plan and tools. Participants will be asked to complete a posttest and an evaluation form after the training session in order to evaluate their understanding and gather feedback from them.

In the sixth month, the investigator will analyst feedback from staff and specialists, then the investigator will modify the guideline in order to optimize the outcome and reduce the risks. Staff will be reminded and encouraged in following the guideline in this month in order to prepare them for the change of practice in the near future.

4.2 Pilot Study Plan

A pilot study will be carried out after granting approval from the organization and obtaining support from people of managerial and operation level. A pilot study is important as it can give advance warning about where the main project could fail, where the protocols may not be followed, or whether proposed methods or instruments are inappropriate or too complicated (Teijlingen van E. & Hundley V., 2001). In contrast, it can prove to the administrative level that the project is worth to be launched.
4.2.1 Objectives

1. To evaluate the feasibility of the innovation and guideline by using the precolonoscopy videotaped information, the PSQ and the STAI-S.

2. To evaluate the compliance of staff on implementing the precolonoscopy videotaped information.

3. To evaluate the acceptance of the precolonoscopy information among staff.

4. To investigate any unexpected outcome and difficulty to be encountered during the process.

5. To investigate the appropriateness of assessment tools chosen.

4.2.2 Time Frame

The estimated duration of the pilot study is eight weeks and it will be carried out the week after the implementation period.

The first week will be used to introduce the pilot study to the involving staff. Since this is a pilot study, therefore it will involve only a few staff in the target setting to minimize disturbance of the normal routine in the target setting.

The trial run will be carried out in the following five weeks. Data to be collected in these five weeks is 10% of the total population of colonoscopy in the target setting per year. The population is adequate to review the significance. In the last two weeks, the working group will collect all the data and analyst the data. A report of the pilot study with comments and advises will be prepared and guideline will be refined according to the report.
4.2.3 Outcome measures and Data Collection

Patient’s satisfaction level is evaluated by the patient satisfaction questionnaires (PSQ). Patients will be invited to complete the PSQ after they are fully awakened from sedation after colonoscopy. In this pilot study, patients will be asked to rate each question in the PSQ to review the importance of each question in patient’s point of. In addition, there will be an item added in the PSQ to encourage patients to write down their feeling and suggestion so qualitative data is obtained to review any unexpected outcome.

Patient’s anxiety level will be assessed by the Spielberger State-Trait Anxiety Inventory (STAI). Patients will be instructed to completed the STAI-State before and after watching the precolonoscopy videotape.

Staff acceptance will be evaluated by inviting the involving staff to a meeting hold by the working group in the seventh week and staff compliance will be assessed by APN’s observation.

4.2.4 Refining the Guideline

Data analyst will be performed in the last two weeks of the Pilot Study period. After meeting with the staff involves in the seventh week, the guideline will be refined and will be ready to be launched. All the endoscopy nurses in the target setting will be invited to join a meeting hold by the working group in the last week. The result of the pilot study and the refined guideline will be presented to the endoscopy nurses. They are encouraged to clarify any question before the guideline is launched. A written report and the final version of the guideline will
be submitted to the administrative level and will be kept in the conference room of the target setting for quick reference and documentation.

4.3 Evaluation Plan

As mentioned, this is an evidence-based protocol of using videotaped information reparation in reducing anxiety level and promoting satisfaction in patients having colonoscopy. The primary outcome is to reduce the anxiety level among patients undergoing colonoscopy while promoting satisfaction level among this group of patients is the secondary outcome. Therefore, in the following evaluation plan, the primary outcome is the main focus for the effectiveness of the innovation. Furthermore, the cost of implementation, the cost saved from the innovation, patient’s comment and staff’s competency and compliance are measured in the evaluation.

4.3.1.1 Quantitative Evaluation

Most of the outcomes can be quantified and be evaluated, for example the anxiety level, satisfaction level and cost. In the following session, the plan of these outcomes is to be discussed.

As mentioned in the previous chapter, State anxiety is experienced periodically when an individual is stress, which is a transitory emotional state. It is altered from moment to moment; therefore, lowering the STAI-State is the goal of the innovation. Patients will be invited to complete the STAI-State before and after watching the videotaped information.
The PSQ developed by the investigator will be used to evaluate patient’s satisfaction level towards the innovation. Validation is done by the Chief Endoscopist and an APN. The goal is to increase the satisfaction level among patients. Patients will be invited to complete the PSQ after they are fully awakened from sedation after colonoscopy.

The data collected from the STAI-State and PSQ will be analyzed by the investigator. A study report will be generated quarterly in the first year to ensure the effectiveness of the guideline.

Total cost involving in the guideline is also an indicator for evaluation. The goal is to minimize the cost spend in repeating colonoscopy due to anxiousness, cost of extra sedation and cost of managing complication, for example cost of emergency operation and unnecessary hospitalization.

**4.3.1.2 Qualitative Evaluation**

Although some of the data cannot be quantified, they are useful for evaluating the guideline. Therefore, qualitative evaluation should be included.

In order to collect data that is not included in the quantitative evaluation, an open-ended question is included in the PSQ by asking for patient’s suggestion and comment towards the innovation. Besides, the competency among staff will be evaluated by interviewing staff in different ranks. In addition, the central audit team of the Central Nursing Department of the target hospital is invited to evaluate the compliance of staff to the innovation periodically.
4.3.2 Sample Size

With referencing to the study conducted by Ruffinengo C., Versino E., Renga G. (2009), a sample size of 64 is able to review the significance of the result (p=0.00001) with a power of 0.80 and a significance of 95% and the different between the average levels of STAI is equal to or larger than 7.

4.3.3 Timelines

There are roughly 64 colonoscopy cases per week in the target setting. In order to collect adequate data as the control group, all eligible patients undergoing colonoscopy are invited to participate in the study by completing the STAI-S and PSQ two weeks before the implementation of the new guideline. After the new guideline is implemented, all eligible patients will be invited to participate in the study and data of the intervention group will be obtained within two weeks afterwards.

Data will be collected and analyzed by the working group. A report will be generated four weeks after the data is collected from the intervention group in order to evaluate the significance of the guideline according to the score of the PSQ and STAI-State.

4.3.4 Basis for Implementation

The guideline is considered to be effective on the basis of outcomes mentioned. As mentioned in the beginning of chapter 4.3, reducing the anxiety level is the main outcome and determinant of the innovation. The effectiveness of
the innovation is determined by decreasing 7 in the STAI-State score. According to the literatures reviewed, all of the five studies shown a positive result on reducing the STAI score with the innovation (Bytzer P. & Lindeberg B., 2007; Callaghan P. & Chan H.C., 2001; Gunay E. et al., 2015; Luck A. et al., 1999; Ruffinengo C., Versino E., Renga G., 2009). It is expected that patients who receive precoloscopy videotaped information will show a significant decrease in the anxiety level. Besides, the secondary outcome, patient’s satisfaction level, should also be considered. The effectiveness of the innovation is determined by increasing the patient satisfaction score. According to the literatures reviewed, there are three studies (Callaghan P. & Chan H.C., 2001; Gunay E. et al., 2015; Ruffinengo C., Versino E., Renga G., 2009) concerning patient’s satisfaction level and all of them shown a positive result on the score. Therefore, it is also expected that patients who receive precoloscopy videotaped information will show a significant increase in patient’s satisfaction score. In addition, the innovation can be continued if there is no complication occurs related to the innovation.
<table>
<thead>
<tr>
<th>Bibliographic citation / Study type (Study quality)</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bytzer P., Lindeberg B. (2007) / RCT (+)</td>
<td>Outpatients scheduled for colonoscopy; Understanding Danish; Have time for watching video in centre. (n=200)</td>
<td>A five-minute video about the procedure, cleaning process and post procedure care information in addition to the usual information were given to the control group showing in a separated room. (n=72)</td>
<td>Usual verbal and written information, including a separate standardized information sheet about the colonoscopy and the cleaning process. (n=90)</td>
<td>3-20 days before colonoscopy</td>
<td>Primary 1) Patients’ anxiety level (STAI-Trait score, mean±SD) 2) Patients’ anxiety level (STAI-State score, mean±SD) 3) Patients’ overall tolerability of colonoscopy, % 4) Patients’ pain level, mean±SD 5) Patients’ willingness to undergo colonoscopy again Secondary 6) Colonoscopy outcome by endoscopist, mean 7) Colonoscopy outcome by nurse, mean 8) Procedure time, minutes 9) Colonic cleaning, mean 10) Amount of Midazolam, mg 11) Amount of Fentanyl, mcg</td>
<td>1) -0.1±0.4 (p=n.s.) 2) -0.9±0.4 (p=n.s.) 3) +4 (p=n.s.) 4) +0.3±0.3 (p=n.s.) 5) -0.6 (p=n.s.) 6) +1 (p=n.s.) 7) +0.5 (p=n.s.) 8) +0.8±3.8 (p=n.s.) 9) 0 (p=n.s.) 10) +0.1 (p=n.s.) 11) +13 (p&lt;0.02)</td>
</tr>
</tbody>
</table>

RCT=Randomized controlled trial; n.s.=Non-significance; SD=Standard deviation
<table>
<thead>
<tr>
<th>Bibliographic citation / Study type (Study quality)</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
</table>
| Luck A. et al. (1999) / RCT (+++) | All patients scheduled for colonoscopy; understanding English; age above 16; no mental impairment (n=150) | A ten-minute video about the procedure in a non-medical language in addition to the usual information were given to the control group showing in a separated room. (n=72) | A separate, standardized information sheet about colonoscopy. (n=78) | 7 days before colonoscopy | 1) Patient’s anxiety score (STAI form, mean (95% CI))  
2) Patient’s understanding on colonoscopy (knowledge questionnaires, mean (95% CI)) | -0.73 (-1.12 to -0.34)  
+1.57 (+1.57 to +1.57) (p=0.0001) |

RCT=Randomized controlled trial; n.s.=Non-significance; SD=Standard deviation
<table>
<thead>
<tr>
<th>Bibliographic citation / Study type (Study quality)</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Callaghan P., Chan HC. (2001) / RCT (1)</td>
<td>Outpatients for gastroscopy for the first time; aged 18-65; understanding Chinese; mentally able to understand the study information and sign the consent form. (n=30)</td>
<td>A five-minute video about the procedural and sensory information produced by the hospital’s surgical unit in a separated room individually. (n=15)</td>
<td>A pamphlet with detailed written procedural and sensory information developed by the researchers in a separated room individually. (n=15)</td>
<td>Before the procedure was done.</td>
<td>1) Mean arterial blood press (mean±SD) 2) State anxiety score (mean±SD) 3) Patient’s satisfaction level (mean±SD)</td>
<td>1) -1.46±4.49 (p=n.s.) 2) -0.54±0.1 (p=n.s.) 3) 2.34±1.21 (p=n.s.)</td>
</tr>
</tbody>
</table>

RCT=Randomized controlled trial; n.s.=Non-significance; SD=Standard deviation
<table>
<thead>
<tr>
<th>Bibliographic citation / Study type (Study quality)</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
</table>
| Günay L. et al. (2015) / RCT(++)                 | Patients to whom bronchoscopy was indicated; age above 18; understanding Turkish; patients in stable condition who were able to cooperate; patients who were literate; mentally fit without using any anxiolytic drugs; patients who signed the informed consent. (n=150) | Same informed consent as control group. Then, a multimedia presentation included visual, audio, video and animation with information for bronchoscopy was shown. (n=75) | A Turkish written informed consent form prepared by Turkish Thoracic Society. Medical support to make the patients really understand the written informed consent by a chest physician. (n=75) | On the procedural day. | 1) Patients' anxiety level (STAI-S score, mean±SD)  
2) Patient's satisfaction level (mean±SD)  
3) Consumption of sedative used (mg, mean±SD)  
4) Duration of procedure (minute, mean±SD) | 1) -3.98±1.54 (p<0.001)  
2) 10.52±0.35 (p<0.001)  
3) -0.7±0.01 (p<0.001)  
4) -2.26±2.74 (p<0.045) |

RCT=Randomized controlled trial; n.s.=Non-significance; SD=Standard deviation
<table>
<thead>
<tr>
<th>Bibliographic citation / Study type (Study quality)</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ruffinengo C., Versino L., Renga G. (2009) / RCT (++)</td>
<td>Hospitalized patients with previous history of acute myocardial infarction or angina and indicating the necessity to perform an elective coronaryography; understanding Italian; aged over 18. (n=120)</td>
<td>An informative video shown on admission as an integration to the standard care that the control group has. (n=48)</td>
<td>Orientation of the ward setting, an interview with the doctor and the nurse, pre-operative shave and venous catheter placement, blood tests, potential therapy and fasting from midnight. (n=45)</td>
<td>5/10 minutes before the intervention</td>
<td>1) Patients’ anxiety level (STAI-State score, WMD) 2) Patients’ satisfaction level of receiving information (VAS, WMD)</td>
<td>1) -8.24 (p=0.00001) 2) +22.23 (p=0.00001)</td>
</tr>
</tbody>
</table>

RCT=Randomized controlled trial; n.s.=Non-significance; SD=Standard deviation
Table 2 Table of Critical Appraisal for Reviewed Studies

<table>
<thead>
<tr>
<th>Methodology Checklist 2: Controlled Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SECTION 1: INTERNAL VALIDITY</strong></td>
</tr>
<tr>
<td><strong>In a well conducted RCT study...</strong></td>
</tr>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).  
No  
There is 38 missing data after randomization was done.

1.10 Where the study is carried out at more than one site, results are comparable for all sites.  
Not applicable  
There was only one site.

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th>Question</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>How well was the study done to minimise bias?</td>
<td>Acceptable (+)</td>
</tr>
<tr>
<td>Code as follows: 1</td>
<td></td>
</tr>
<tr>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>It may not totally because of the intervention, as majority of the patients recruited were women. Many studies reported that women had significantly higher situational anxiety scores than men, and found the procedure significantly more painful. These may contribute to the result of the study.</td>
</tr>
<tr>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
</tr>
<tr>
<td>Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
<td></td>
</tr>
</tbody>
</table>

The effect that additional information has on patient anxiety has been controversial. However, tailoring the information according to the patient’s coping style has been shown to reduce anxiety and recovery time in connection with colonoscopy.
**Methodology Checklist 2: Controlled Trials**


### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study...**

<table>
<thead>
<tr>
<th></th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.(^i)</td>
</tr>
<tr>
<td></td>
<td>The PICO are clearly stated</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomised.(^ii)</td>
</tr>
<tr>
<td></td>
<td>Patients were randomly assigned to the groups with thorough shuffled marked cards into sequentially numbered</td>
</tr>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used.(^iii)</td>
</tr>
<tr>
<td></td>
<td>The allocation was done via sealed, opaque envelopes</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept ‘blind’ about treatment allocation.(^iv)</td>
</tr>
<tr>
<td></td>
<td>The study didn’t mention about the blindness of the procedure. It mentioned that the self-assessment anxiety and knowledge questionnaires were marked by a study organizer who was unaware of the randomization status of the participant only.</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial.(^v)</td>
</tr>
<tr>
<td></td>
<td>There were no differences in baseline characteristics between groups as shown in Table 1.</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.(^vi)</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way.(^vii)</td>
</tr>
<tr>
<td></td>
<td>The information was obtained with the Spielberger state-anxiety self-evaluation questionnaire from the state-trait anxiety inventory and a validated knowledge questionnaire. The outcomes were analyzed by using linear-regression model, chi-squared test.</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?(^viii)</td>
</tr>
<tr>
<td></td>
<td>All patients recruited were included in this study.</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).(^ix)</td>
</tr>
<tr>
<td></td>
<td>All patients remained in their same group.</td>
</tr>
</tbody>
</table>
### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th>How well was the study done to minimise bias? Code as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>High quality (+++) ✓</td>
</tr>
</tbody>
</table>

Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

- The Spielberger state-anxiety self-evaluation questionnaire from the state-trait anxiety inventory was a widely used tool for anxiety scoring and being validated by many studies. The data collected was analysed with linear-regression model to evaluate the relationship among variables. The p-value show smaller than 0.05 in all aspects which proved that the study result was contributed by the interventions. It claimed that the factors significantly affecting anxiety immediately before colonoscopy were the anxiety score at enrolment and whether or not the patient had watched the video.

Are the results of this study directly applicable to the patient group targeted by this guideline?

- Yes

**Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

- The patients assigned to watch the video in this study showed a significant decrease in anxiety.
- The dual benefit of the video in the improvement of knowledge and the reduction of anxiety is best shown in the patients who had higher initial anxiety scores. However, there was no proof on the relationship between knowledge gain and anxiety ceased.
- The effect that information provided during the consent process has on anxiety is controversial. There has been belief that the provision of extra information, particularly about risks and complications, may cause patients undue anxiety as the author suggested.
Methodology Checklist 2: Controlled Trials


**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th></th>
<th>In a well conducted RCT study...</th>
<th>Does this study do it?</th>
</tr>
</thead>
</table>
| 1.1 | The study addresses an appropriate and clearly focused question. | Yes  
The PICO were clearly stated. |
| 1.2 | The assignment of subjects to treatment groups is randomised. | Yes  
Patients were randomly assigned to the groups by researchers. |
| 1.3 | An adequate concealment method is used. | No  
No concealment method was reported. |
| 1.4 | Subjects and investigators are kept 'blind' about treatment allocation. | Can’t say  
The presence of blinding was not mentioned. |
| 1.5 | The treatment and control groups are similar at the start of the trial. | Yes  
The randomization groups were well balanced with respect to age, gender, prior knowledge level of gastroscopy as shown in Table 1. |
| 1.6 | The only difference between groups is the treatment under investigation. | Yes |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Yes  
The information was obtained with the Chinese State-Trait Anxiety Inventory and a validated patients’ satisfaction questionnaire. The outcome were analyzed by using t-test. |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | 0%  
All patients recruited were included in this study. |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Not applicable  
All patients remained in their own group. |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Not applicable  
There was only one site. |
### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th><strong>How well was the study done to minimise bias?</strong>&lt;br&gt; <em>Code as follows:</em></th>
<th>Acceptable (+) X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>It was mentioned that there was evidence showing that a sample size of 30 is sufficient to detect a medium effect size in different between psycho-education interventions.</td>
</tr>
<tr>
<td><strong>Are the results of this study directly applicable to the patient group targeted by this guideline?</strong></td>
<td>No&lt;br&gt;Because only 30 Chinese in Hong Kong were studied.</td>
</tr>
</tbody>
</table>

**Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

- It was suggested that Chinese characteristics might affect the outcome as Chinese tends to be disinclined to show their unawareness and thus few questions were raised.
- It was also suggested that behavioral information might impact more upon anxiety than the procedural and sensory information included in this study.
- There was insufficient time for patients to digest the information adequately just before the procedure was done.
# Methodology Checklist 2: Controlled Trials


## SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study...</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes \nThe PICO were clearly stated.</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td>Yes \nPatients were randomly assigned to the groups with numbered envelop randomly.</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Yes \nThe patients were divided into two groups via the sealed and numbered envelope technique randomly by a chest physician.</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept 'blind' about treatment allocation.</td>
<td>Yes \nIt was a single blinded study as the bronchoscopists and anesthesiologists were not aware of the groups.</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes \nThe randomization groups were well balanced with respect to demographic characteristics, preliminary diagnosis, appointment duration, previous history of bronchoscopy and other experiences of endoscopic intervention.</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes \nThe information was obtained with state anxiety part of the State and Trait Anxiety Inventory, lieret scale and Ramsay scale. The outcomes were examined with SPSS software with the Kolmogorov-Smirnov test, Fischer exact-test, Chi-square test, Student’s test, Mann-Whitney U test and Multiple linear regression models.</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>0% \nAll patients recruited were included in this study.</td>
</tr>
</tbody>
</table>
### 1.9
All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).<sup>1</sup> Not applicable
All patients remained in their own group.

### 1.10
Where the study is carried out at more than one site, results are comparable for all sites.<sup>ii</sup> Not applicable
There was only one site.

---

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>How well was the study done to minimise bias?</td>
<td>High quality (+++) ✔</td>
</tr>
<tr>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>The State-Trait Anxiety Inventory was used which was a widely used tool for anxiety scoring and being validated by many studies. The data collected was analysed with linear-regression model and various test from SPSS to evaluate the relationship among variables. The p-value shown smaller than 0.05 in all aspects which proved that the study result was contributed by the interventions.</td>
</tr>
<tr>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

The author suggested that many patients do not read the written information forms exactly and do not fully understand the provided information. Therefore, it is believed that electronic media are the good alternatives to overcome the deficiencies of information leaflets.

It is also believed that using multimedia information can decrease adverse effects of higher doses of sedation together with relaxing patients about the procedure.
### Methodology Checklist 2: Controlled Trials


#### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study...</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question. (^i)</td>
<td>Yes</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised. (^ii)</td>
<td>Yes</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used. (^iii)</td>
<td>Yes</td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept ‘blind’ about treatment allocation. (^iv)</td>
<td>Can’t say</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial. (^v)</td>
<td>Yes</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation. (^vi)</td>
<td>Yes</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way. (^vii)</td>
<td>Yes</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? (^viii)</td>
<td>22.5%</td>
</tr>
<tr>
<td>1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). (^ix)</td>
<td>No</td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites. (^x)</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>How well was the study done to minimise bias? Code as follows:</td>
<td>High quality (++)?</td>
</tr>
<tr>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>The State-Trait Anxiety Inventory was used which was a widely used tool for anxiety scoring and being validated by many studies. The data collected was analysed with Bartlett test, ANOVA test and Chi-square test by using EpilInfor 3.3.2. version. The p-value shown smaller than 0.05 in all aspects which proved that the study result was contributed by the interventions. Meanwhile, the sample size achieved the value larger than 7 (difference between the average levels of anxiety), with a power and a significance of 95%.</td>
</tr>
<tr>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

The author suggested that for further research, it would be interesting to measure anxiety during the procedure. Anxiety level could also be measured immediately on admission in order to allow pre-post comparisons between the two groups. It was also suggested that the quality of the video cannot be standardized easily which means that better or worse results could depends on the quality of the product. A test should be ran to verify video usability.
結腸內視鏡(大腸鏡)檢查簡介

簡介
結腸內視鏡檢查，俗稱大腸鏡檢查，是用一支柔軟內視鏡檢查下腔消化道，
包括迴腸末端、盲腸、結腸各部位、直腸及肛門疾病的最佳方法。病人懷疑
患有大腸疾病如癌症、出血或大便帶膿血、大便習慣改變、長期下腹或
便祕、排便困難等情況均應接受大腸鏡檢查。大腸鏡檢查除能發現病理原
因，並能同時通過各種輔助儀器，對病源作詳細樣本化驗及進行治療，例
如切除大腸息肉。

檢查過程
在檢查前，醫生先給病人注射適量的鎮靜劑，此能減低病人的焦慮及檢查
時所引起的不適。醫生同時會替病人肛門部位塗上潤滑劑。醫生隨著將一
支柔軟，直徑約為1.5公分之內視鏡由病人肛門放進體內進行檢查。檢查期
間，病人均保持清醒。視乎病人個別情況，一般來說，整體檢查需時約10-45
分鐘。在一些複雜的個案而需要特別治療者，所需之時間將會更長。

風險或併發症
檢查期間病人多感到腹部氣腫及輕度不適，較嚴重之併發症包括腸道穿
孔、出血、心臟併發症、感染及急性腸閉塞等，一般來說機會少於百份之
一。各併發症發生之機會隨著病人不同之情況及治療方法而有異。病人如
要接受內鏡治療，如息肉切除、內鏡止血、腸腫及支架放置等則出現嚴重
併發症之機會亦大幅提高。如併發症出現，病人需接受外科手術治療，
嚴重者可導致病人死亡。病人應主動詢問主診醫生以明瞭詳情。

檢查前準備
病人在檢查前三日必須食用低纖維餐，如病人服用鐵質補劑，須在檢查前
三至四日停服，病人必須在先服用強力清腸藥水以將大腸內之大便全部排出，使醫生能更準確地觀察大腸壁之病變。清腸藥水之劑量及服用辦法因應病人需要而不同，故病人須依照指示準時服用。如病人未能完成放腸程序，則有礙檢查進行。病人如有其他疾病如糖尿病、高血壓、心臟病或懷孕等，須告訴醫護人員並聽從其指示服藥。病人亦應提供現所服用藥物的詳情，特別是某些影響凝血的藥物及任何過敏反應資料。門診病人不宜親自駕車前來；亦應避免在檢查前飲酒、抽煙或服用不當份量的鎮靜藥物。年老、行動不便的病人宜由家人陪伴前來檢查。

檢查後須知
於檢查後，待麻醉藥或鎮靜劑藥力減退後病人便可進食。如病人接受鎮靜劑注射，則整天不可操作重型機器、簽署法律文件或駕駛，以防意外發生。病人應主動查詢檢查結果及日後覆診日期，並依照醫護人員指示完成藥物療程。

檢查後跟進
在檢查後如病人出現輕微不適，或對檢查結果、服藥有疑問者，應於辦公時間內致電“內窩鏡中心”查詢；但如出現嚴重事故，如大便出血、劇烈腹痛等，則應到就近急症室求診。

備註
本單張只提供有關檢查的基本資料，可能發生的風險或併發症不能盡錄。某類病人的風險程度亦為不同，如有查詢，請聯絡你的醫生。
結腸鏡檢查及息肉切除術

簡介
結腸鏡檢查可以較詳細檢查結腸黏膜。結腸鏡檢查是一種常見的診斷法，可以由肛門進入結腸，醫生進行檢查時，可以發現結腸出現任何問題，包括息肉。如發現息肉，可切除，以避免可能的癌症發展。

準備工作
- 檢查前一天及日內只可進食流質食物，如粥
- 當天清晨用潔膚或用潔膚溶液清洗大腸
- 如作任何藥物對體質反應，請通知診所護士
- 應簽署手術同意書

過程
- 服用洗腸藥或在結腸鏡檢查前
- 病人需側臥及屈左膝
- 有需要時，醫生會注射鎮靜劑
- 然後將已裝好鏡的結腸鏡插入肛門檢查結腸黏膜，病人可能會有不適的感覺，但不必感到疼痛
- 整個過程約需十五分鐘至一小時

護理及建議
- 檢查後一般可恢復正常飲食
- 可用普通貢茶沖服，飲用果汁等
- 病人若出現流血，應通知隔離病房醫生

併發症
結腸鏡檢查及息肉切除術一般都是安全的，但仍可出現下列的併發症：
- 醫療處置不周，引致腹瀉
- 進行手術後不適，腸蠕動減弱
- 取結腸鏡或切除息肉的地方可能有輕微出血，一般會自行止血

如有任何問題，請向你的主治醫生query
以上資料由腸胃腸科外科提供

COLONOSCOPY AND POLYECTOMY

Introduction
Colonoscopy is the procedure of viewing the inside of the large bowel using a long flexible fibreoptic endoscope. If a small polypoid growth (polyp) is known to be present in the colon, it can be removed (polypectomy) if the growth looks suspicious, biopsy of the growth will be done and sent on for laboratory analysis.

Preparation
- A soft diet such as congee with low fibre for two days before the procedure.
- Prepare the night before the procedure to clear the bowel
- Please inform the doctor or nurse if you have history of drug allergy
- A written consent is required

Procedure
- Colonoscopy and polypectomy is usually performed in the Endoscopy Unit with or without intravenous sedation
- Your doctor will put you in a lateral position with the hand and leg flexed
- The lubricated endoscope is then inserted into the large bowel through the anus
- You may feel a bit discomfort when air is pulsing in to open up the lumen of the bowel for proper vision
- This procedure may last for 15 minutes to one hour depending mainly on the anatomy of the large bowel

Care and Advice
- Under most situation, normal diet may resume after the effect of sedation is worn off. Your doctor will assess you
- If severe abdominal pain, fever and massive rectal bleeding is experienced, immediately return to the Accident & Emergency Department of Hospital

Complications
- Bleeding caused due to bleeding is expected in the first two days after polypectomy or biopsy. Bleeding will rarely be severe
- bowel perforation occurred in less than 0.1%, which may require an operation to repair the hole.

Should these be any queries, consult your doctor in-charge.
Information provided by Department of surgery, Queen Mary Hospital

64
### Methodology Checklist 2: Controlled Trials

**Study identification** (Include author, title, year of publication, journal title, pages)

<table>
<thead>
<tr>
<th>Guideline topic</th>
<th>Key Question No</th>
<th>Reviewer</th>
</tr>
</thead>
</table>

**Before** completing this checklist, consider:

1. Is the paper a randomised controlled trial or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:** 1. Paper not relevant to key question □ 2. Other reason □ (please specify):

#### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study...**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Can't say</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4 Subjects and investigators are kept 'blind' about treatment allocation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.10 Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

*File name: Checklist 2 - Controlled Trials*  
*Version 2.0*  
*Produced by: Carolyn Seith*  
*Page 1 of 3*  
*Review date: None*
2.1 How well was the study done to minimise bias?

High quality (++): □
Acceptable (+): □
Unacceptable – reject: 0 □

2.2 Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?

2.3 Are the results of this study directly applicable to the patient group targeted by this guideline?

2.4 Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

1 Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

2 Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study.

3 Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%.

4 Blinding refers to the process whereby people are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. It can be carried out up to three levels. Single blinding is where patients are unaware of which treatment they are receiving. In double blind studies neither the clinician nor the patient knows which treatment is being given. In very rare cases studies may be triple blinded, where neither patients, doctors, nor those conducting the research are aware of which patients received which treatment. The tighter the level of blinding the better the quality of the study.

5 Patients selected for inclusion in a trial must be as similar as possible. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin, or co-morbid conditions. These factors may be covered by inclusion and exclusion criteria rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

6 If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. If groups were not treated equally, the study should be rejected unless no other evidence is available. If the study is used as evidence it should be treated with caution.

7 The primary outcome measures used should be clearly stated in the study. If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

8 The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as
well as how many. It should be noted that the drop out rate may be expected to be higher in studies conducted over a long period of time. A higher drop out rate will normally lead to downgrading, rather than rejection of a study.

- In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated irrespective of the treatment they actually received. (This is known as intention to treat analysis.) If it is clear that analysis was not on an intention to treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

- In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.

- Rate the overall methodological quality of the study, using the following as a guide: High quality (++): Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. Acceptable (+): Most criteria met. Some flaws in the study with an associated risk of bias, Conclusions may change in the light of further studies. Low quality (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.
Appendix 3

In search of evidence, we need to aware of the level of evidence provided by individual studies. Apart from the quality of the study, there can be hierarchy of evidence in terms of the design. There are many hierarchies of evidence and one described in Melnyk & Fineout-Overholt (2005) is

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
<td>Evidence from systematic review of meta-analysis of all relevant randomized controlled trials (RCTs), or evidence-based clinical practice guidelines based on systematic reviews of RCTs</td>
</tr>
<tr>
<td>Level II</td>
<td>Evidence from at least one well-designed RCT</td>
</tr>
<tr>
<td>Level III</td>
<td>Evidence from well-designed controlled trials WITHOUT randomization</td>
</tr>
<tr>
<td>Level IV</td>
<td>Evidence from well-designed case-control and cohort studies</td>
</tr>
<tr>
<td>Level V</td>
<td>Evidence from systematic reviews of descriptive and qualitative studies</td>
</tr>
<tr>
<td>Level VI</td>
<td>Evidence from a single descriptive or qualitative study</td>
</tr>
<tr>
<td>Level VII</td>
<td>Evidence from the opinion of authorities and/or reports of expert committees</td>
</tr>
</tbody>
</table>
Appendix 4

1) Manpower cost

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount (HK Dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average manpower cost of committee member of creating the</td>
<td>194* x 8 hours x 3 RN x 2 days x 194</td>
</tr>
<tr>
<td>videotaped information DVD</td>
<td>= 49,664</td>
</tr>
<tr>
<td>Total</td>
<td>49,664</td>
</tr>
</tbody>
</table>

* The salary of RN in the committee in the target setting is ranged from point 15 to 25 under the Master Pay Scale of the Hospital Authority. The median point is point 20 and the salary is $34,180 and the hourly salary is $194.

2) Equipment cost for running the new innovation

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount (HK Dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVD player</td>
<td>1,000</td>
</tr>
<tr>
<td>DVD 2 sets</td>
<td>5 x 2 sets = 10</td>
</tr>
<tr>
<td>Total</td>
<td>1,010</td>
</tr>
</tbody>
</table>

3) Consumable Cost for running the new practice yearly

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount (HK Dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper/ Photocopying</td>
<td>2 x 20 patients x 208 days = 8,320</td>
</tr>
<tr>
<td>Extra stationaries</td>
<td>5 x 208 days = 1,040</td>
</tr>
<tr>
<td>Total</td>
<td>9,360</td>
</tr>
</tbody>
</table>

4) Evaluation Cost yearly

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount (HK Dollars)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper used for questionnaire and STAI</td>
<td>2 x 20 patients x 208 days = 8,320</td>
</tr>
<tr>
<td>Total</td>
<td>8,320</td>
</tr>
</tbody>
</table>
Evidence-based Practice Guideline on

Precolonoscopy Preparation Information in Video Format

January 2016
Content

1. Guideline Information
2. Background of the Guideline
3. Aims and Objectives of the Guideline
4. Recommendations
5. References
1. Guideline Information

Title: Evidence-based Practice Guideline on Precolonoscopy Preparation

Information in Video Format

Date released: January 2016

Edition: 1st Edition

Developed by: Cheung Ho Yee, R.N.
2. Background of the Guideline

Anxiety is commonly found in patients undergoing colonoscopy. Anxiety before colonoscopy may have adverse outcomes (Bytzer P. & Lindeberg B., 2007). An effective, comprehensive and standardized way can provide information to patients effectively and efficiently. Pearson et al. (2005) suggested that videotaped information assures a standard level of teaching. It is also proven that videotaped information can lower patient’s anxiety level and increase patient’s satisfaction level (Bytzer P. & Lindeberg B., 2007; Callaghan P. & Chan H.C., 2001; Gunay E. et al., 2015; Luck A. et al., 1999; Ruffinengo C., Versino E., Renga G., 2009). The guideline is developed with reference of the five selected studies. The level of evidence of each study and the grade of each recommendation are evaluated by referring to the Scottish Intercollegiate Guidelines Network (SIGN). A level of 1++ to 4 is assigned to level of evidence and a grade of A, B, C or D is assigned to grade of recommendation according to the “SIGN 50: A guideline develop’s handbook Annex B: Key to grades of recommandations” (Scottish Intercollegiate Guidelines Network, 2014).
3. Aims and Objectives of the Guideline

3.1 Aim

The aim of the Guideline is to provide nurses a clear instruction on utilizing the videotaped information in order to improve patients’ anxiety level and satisfaction level.

3.2 Objectives

1. To summarize the clinical evidence for using a videotaped precolonoscopy information.
2. To formulate a clear instruction on utilizing the videotaped precolonoscopy information.
3. To generate a workflow for implementing the videotaped precolonoscopy information in the endoscopy centre.
4. Recommendations

Recommendation 1

Format of providing information

Information in videotaped format is used rather than using written information alone.

Grade of Recommendation: A

Available Evidence:

All reviewed studies provide information in videotaped format and all the reviewed studies shown a lower in the Spielberger State-Trait Anxiety Inventory (STAI) score (Gunay E. et al., 2015; Luck A. et al., 1999; Ruffinengo C., Versino E., Renga G., 2009) <Level 1++> (Bytzer P. & Lindeberg B., 2007; Callaghan P. & Chan H.C., 2001) <Level 1+> and improve in patient’s satisfaction (Gunay E. et al., 2015; Luck A. et al., 1999; Ruffinengo C., Versino E., Renga G., 2009) <Level 1++> (Callaghan P. & Chan H.C., 2001) <Level 1+>.

It is also suggested by Gunay E. et al. (2015) <Level 1++> that many patients do not read the written information and cannot fully understand the information provided, videotape is a good alternative to overcome the deficiencies.

Recommendation 2

Timing of providing videotaped information

Information should be provided on the same day of colonoscopy and before the procedure is done.
Grade of Recommendation: B
Available Evidence:

Patients received the videotaped information on the same day when the procedure was done (Callaghan P. & Chan H.C., 2001).

**Recommendation 3**

**Content to be excluded**

**Risks and complications on colonoscopy should be excluded.**

The purpose of the videotaped information is to lower the anxiety level, improve patient’s satisfaction and promoting their cooperation during the procedure. All the related information including the risks and complications are mentioned in the leaflet about colonoscopy was given upon the appointment is made.

Grade of Recommendation: A
Available Evidence:

It was reported that mentioning risks and complications in the videotaped information may contribute to increase patient’s anxiety level (Luck A. et al., 1999) <Level 1++> (Bytzer P. & Lindeberg B., 2007) <Level 1+>.

**Recommendation 4**

**Frequency on providing the videotaped information**

The videotaped information should be shown in a continuous way in the waiting area.

Repeating of the same videotaped information in the waiting area should be done to make sure all the patients are able to received the
information properly any time when they arrive the centre. Meanwhile, it allows time for patients to receive and digest the information in an adequate time.

Grade of Recommendation: B

Available Evidence:

Callaghan P. & Chan H.C. (2001) suggested that it does not have enough time for patients to digest the information received if patients watch the information once only.

**Recommendation 5**

**Evaluation tools**

The effectiveness of the videotaped information is evaluated by patients’ anxiety level with the STAI-S score and by patients’ satisfaction level with patient satisfaction questionnaire.

Grade of Recommendation: A

Available Evidence:

All the reviewed studies adopted the STAI for evaluating the anxiety level of patients (Gunay E. et al., 2015; Luck A. et al., 1999; Ruffinengo C., Versino E., Renga G., 2009) <Level 1+++> (Bytzer P. & Lindeberg B., 2007; Callaghan P. & Chan H.C., 2001) <Level 1+> and the satisfaction level of patients was evaluated with the patient satisfaction questionnaire in study by Callaghan P. & Chan H.C. (2001).
References


References


Teijlingen van E. & Hundley V. The Importance of Pilot Study. *Social Research Update* 2001; 35.


Winawer SJ. Natural history of colorectal cancer. *The American Journal of Medicine* 1999; 106(1A): 3S-6S.