Abstract of dissertation entitled

“Evidence-based Intervention Protocol of Using Biofeedback Therapy for Minimizing Post Surgery Bowel Incontinence for Adult Patients”

Submitted by

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In Hong Kong, the number of colon cancer patients has increased over the years. But at the same time, early detection of colon cancer has also become more readily available due to the recent technological advancement and increased accessibility to medical care. In recent years, more patients have become eligible for having curative sphincter saving operation and one of the objectives of this operation is to preserve continence function without stoma formation. However, colon cancer patients’ journeys do not finish after their operation. For instance, they may have bowel disorder after the operation, namely ‘Anterior Resection Syndrome’. This debilitating condition may not be amenable by surgical technique or medical therapy and it affects the bio-psycho-social wellbeing of the patient. One of the responsibilities of nurses is to promote the general wellbeing of the clients. Therefore, in this study, the possible methods of alleviating the condition of Anterior Resection Syndrome among colon cancer patients were inspected. By using strategic search of current evidences, this study found that several primary studies support the use of biofeedback to alleviate the condition. After conducting a comprehensive review of the selected studies, the biofeedback treatment was considered as an appropriate recommendation for the current clinical setting. After assessing the implementation potential of the current practice, an evidence-based protocol with considerations of local factors was established. In addition, in order to minimize resistance on the change of current practice, plans on communicating with stakeholders, pilot study and evaluation were carefully established. The purpose of this study is to provide professional nursing care by using evidence based practice for those in need.
Evidence-based Intervention Protocol of Using Biofeedback Therapy for Minimizing
Post Surgery Bowel Incontinence for Adult Patients

by

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Declaration

I declare that this thesis represents my own work, except where due acknowledgement is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualifications.

Signed ..............................................................................................................................

Cheuk Fan Lam
I would like to thank Dr. William Li, my dissertation supervisor, for his unreserved support in helping me complete this dissertation. I would also like to thank the teachers in this course who open up my vision for the future.

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Chapter 1: Introduction

One of the leading causes of death in Hong Kong is cancer. A report showed that cancer has killed more than 12,000 people per year in Hong Kong in the past 5 years (Centre for Health Protection, 2011). According to the Hong Kong Cancer Registry in 2009, colorectal cancer is the second most common cancer in Hong Kong (Hospital Authority, 2011). It is the second leading cause of cancer death following breast cancer in women and the third leading cause of cancer death following lung and liver cancer in men (Hospital Authority, 2011). The incidence of bowel cancer has been increasing rapidly in recent years and it is predicted that bowel cancer may overtake to become the first in the list in 2015 (Hong Kong Cancer Fund, 2011). Among the locations of colorectal cancer in Chinese, around 54.3% (Xu et al., 2010) to 66.9% (Li & Gu, 2005) of the cancers are located at the rectum. This implies that the number of patients who need the rectal cancer treatment will increase. Surgery is the cornerstone of curative treatment for colon cancer (Kosinski, Habr-Gama, Ludwig, & Perez, 2012; Siegel et al., 2012). It may be used either alone, or in combination with radiotherapy and/or chemotherapy (Siegel et al., 2012). The main aim of the surgery is to remove the primary cancer with adequate margins, regional lymphadenectomy, restoration of the continuity of the gastrointestinal tract by anastomosis (Fry, Mahmoud, Maron, & Bleier, 2012). This surgery can prevent local recurrence and minimize mortality and morbidity such as impotence and bladder dysfunction (Kosinski et al., 2012). However, due to the pelvic anatomy and proximity of adjacent organs to the bowel, such as the urethra, prostate, seminal vesicles, vagina, cervix and bladder, it is challenging to decide how wide the resection margin should be, as there is a consideration of preserving the anal sphincter in order to prevent permanent stoma formation (Fry et al., 2012). Abdominoperineal resection, which is the removal of the rectum and the creation of permanent stoma, was the standard
care for nearly 80 years (Kosinski et al., 2012). However, it brings a permanent stoma, higher local recurrence rate than low anterior resection, problematic perineal wound healing, and the possibility of flap reconstruction (Kosinski et al., 2012). Some modifications have therefore emerged in order to preserve the sphincter and continence and lower the local recurrence rate. Low anterior resection using an intraluminal stapler is the commonest choice of operation, given when it is technically possible for the tumors to be resected with an adequate distal margin (Fry et al., 2012). However, for tumors that cannot be resected with a good resection margin or when the anal sphincter function is compromised, an abdominoperineal resection will be performed instead (Glasgow & Fleshman, 2008). Permanent stoma formation would lead to problems of altered body image, finance, and gastrointestinal symptoms, especially for the married and the less educated, as shown in Sideris et al. (2005) study (2005). Another common problem is the peristomal skin complications. It is troublesome and its consequences are significant from the economic viewpoint (Meisner, Lehur, Moran, Martins, & Jemec, 2012). From both patients’ and surgeons’ views, the quality of life of having permanent stoma is expected to be lower than sphincter saving surgery (Bossema, Stiggelbout, Baas-Thijssen, Van De Velde, & Marijnen, 2008). However, based on the findings from How et al. (2012) study (2012), the quality of life of post-abdominoperineal resection is not necessarily inferior to low anterior resection. So, it may be prejudiced if we stigmatize abdominoperineal resection with a compromised quality of life (Tilney, 2012). Nonetheless, patients often prefer sphincter saving operation even with the risk of fecal incontinence (Bossema et al., 2008) and surgeons would consider minimizing local recurrence, mortality and morbidity (Kosinski et al., 2012). Low anterior resection is performed in first instance and related morbidity, like fecal incontinence, should be addressed.
1.1 Background

One of the aims of having anterior resection with primary anastomosis is to retain anorectal function, which serves as a fecal reservoir and maintains continence (Fry et al., 2012). However, end-to-end anastomosis between the descending colon and the distal rectum or anus may result in significant alteration of bowel habit (Fry et al., 2012). Patients often experience frequent small bowel movements (Fry et al., 2012), incontinence of flatus and feces, urgency, and incomplete evacuation (Avital, 2012). The occurrence of these disorders in patients who have undergone an anterior resection of the colon refers to the ‘Anterior Resection Syndrome’ (Avital, 2012). Literature showed that 30%-60% of patients who had anterior resection would suffer from anterior resection syndrome (Taylor & Morgan, 2011). Additionally, it was reported that low anterior resection (i.e. the anastomotic site is close to the anal verge) would lead to more severe defecation problem than high anterior resection (Guren et al., 2005). Such findings indicate that it is a predictive factor of the development of anterior resection syndrome. Apart from the low anastomotic level, pelvic sepsis and male were also reported to be a predictive factor of anterior resection syndrome (Mikael, Jonas, Sven, & Olle, 2005).

Continence depends on the balanced interaction between plug function, stool consistency, rectal reservoir function, and neurologic sensory or motor function (Kaiser, 2009a). The development of anterior resection syndrome is believed to be due to the replacement of the native rectal reservoir into a more proximal portion of the colon, decreased neorectal volume and compliance (Avital, 2012), spasticity as a consequence of autonomic nerve disruption, and loss of the sensitive anal transition zone in intersphincteric resections (Kosinski et al., 2012; Otto et al., 1996). Therefore, in presence of the anterior resection syndrome, the three elements in maintaining continence, namely, plug deficit, capacity
dysfunction and neurological sensory or motor dysfunction, are considered as impaired (Kaiser, 2009b). Some postulate that anterior resection syndrome arises from the sympathetic denervation of the rectum (G. N. Rao, Drew, Lee, Monson, & Duthie, 1996). Physiologically, the smooth muscles of the rectum remnant are denervated during mesorectal excision and they become hypersensitive to hypogastric plexus and the inferior mesenteric ganglia (G. N. Rao et al., 1996). While volume and rectal compliance are not the factors influencing the functional outcome (Mikael et al., 2005), the only factor that is needed for fecal continence should be the innervation of the sphincter. The innervation of the sphincter should include the sensory and motor nerve fibers, which empty the rectum adequately and produce contraction of the anal sphincter fibers respectively (Fry et al., 2012). Patients suffering from anterior resection syndrome with incontinence symptoms were found to have lower resting anal canal pressure (RAP), hypersensitive rectoanal inhibitory reflex (RAIR) (Mikael et al., 2005; Pietsch, Fietkau, Klautke, Foitzik, & Klar, 2007), decreased squeeze pressure (Mikael et al., 2005), smaller functional rectal capacity (W. G. Lewis et al., 1995; Otto et al., 1996) and poorer rectal sensation (Otto et al., 1996).

Unfortunately, the distorted physiology following low anterior resection may not be recovered even after one year since operation (Williamson et al., 1995). More than that, some patients failed to regain satisfactory anorectal function after the procedure (Williamson et al., 1995). For some patients, symptoms of post anterior resection syndrome may result in severe debility (Avital, 2012). In the study conducted by Vironen, Kairaluoma, Aalto, and Kellokumpu (2006), the authors found that the bowel dysfunction of patients who had undergone anterior resection had significantly impaired their social functioning when compared with their counterparts. In qualitative studies eliciting the experiences and quality of life among patients with anterior resection syndrome, participants stated that, because of their bowel disorder, they lost the confidence to function at a social level and experienced
fear, embarrassment and vulnerability (Desnoo & Faithfull, 2006; Taylor & Morgan, 2011). Patients who have low anterior resection have a lower quality of life than those who undertake abdominoperineal resection (Grumann, Noack, Hoffmann, & Schlag, 2001; How et al., 2012). In addition, because of the stigma associated with incontinence, they are not willing to discuss their problems with others openly (Desnoo & Faithfull, 2006). As they would isolate themselves at home until they feel physically and mentally confident, their social life is impaired (Desnoo & Faithfull, 2006). The patient may be stigmatized by their employers and be discharged to take medical disability (Whitehead, Wald, & Norton, 2001). The patient may have low self-morale and finally isolate themselves (Whitehead et al., 2001).

In order to minimize the severity of anterior resection syndrome, Ludwig (2012) proposed a treatment. The treatment is the reconstruction with a colonic pouch to increase neorectal capacity, use of anti-diarrheal medications to slow GI transit and help in solidifying stool, and use of anti-cholinergic medications to reduce the spasticity of the left colon and neorectum. Few specific surgical techniques are adopted, including J-pouch (Mikael et al., 2005), coloplasty or side to end anastomosis (Baker anastomosis) to increase neorectal volume (Avital, 2012). In a multi-centre trial, J-pouch was not feasible in about 26% of the patients and J-pouch is superior to the coloplasty pouch with respect to the total number of daily bowel movements, pad usage, clustering and fecal incontinence score (Fazio et al., 2007). Despite those techniques were fashioned, the quality of life of patients in the pouch groups was not statistically different than those in the straight anastomosis group and the postoperatively bowel function is similar across the pouch groups and the group with a straight anastomosis after 24 months (Fazio et al., 2007). It seems that these surgical strategies do not give promising effect postoperatively. Conservative treatment will still be the first line therapy to fecal incontinence after the surgery (Lundby & Duelund-Jakobsen, 2011). Bulk-forming medication, such as natural psyllium, methyl cellulose or synthetic
polycarbophil may increase stool consistency and amount of stool in chronic diarrhea related fecal incontinence (Scarlett, 2004), as solid stool is easier to control than loose stool (Lundby & Duelund-Jakobsen, 2011). However, the evidence of using bulk forming agents to alleviate the anterior resection syndrome is limited. In particular, there was only one open label study showed amitriptyline decreases the amplitude and frequency of rectal motor complexes, increases colonic transit time and leads to the formation of a firmer stool that improved continence (Santoro, Eitan, Pryde, & Bartolo, 2000). Antidiarrheal, such as loperamide which increases fluid absorption, colonic transit time and anal resting sphincter pressure (Hanauer, 2008), are used in alleviate the fecal incontinence. The drawback of loperamide is that it tends to be too potent and produce constipation and abdominal pain (Palmer, Corbett, & Holdsworth, 1980) but, statistically, it did not improve daytime leaking in patients after restorative proctocolectomy (Hallgren et al., 1994). There are effective treatments for fecal incontinence on a short-term basis (Sze & Hobbs, 2009). The responsibilities of nurses include addressing the related issue and working with patients to establish the degree of control (Taylor & Morgan, 2011). Diet manipulation, such as avoiding food that provoke loose stool and frequent bowel movements, toileting, skin care strategies and protection of underwear with the use of pads, would be the basic education given to the patients (Desnoo & Faithfull, 2006; "Rectum and anus," 2008; Taylor & Morgan, 2011). Reassuring the patients that their condition would improve with time also helps the patient to adapt the change. Teaching of pelvic floor and sphincter exercises and bowel retraining are also recommended (Taylor & Morgan, 2011). For patients who do not have subsequent improvement in their conditions despite conservative treatment, doctors usually reassure them that the condition would resolve over time with medications. However, the patients may feel overwhelmed and disappointed as the problem often lasts more than a year without a significant improvement, which in turn further compromises their quality of life (Williamson et al., 1995). In intractable
incontinence cases, stoma formation may be needed as the last resort (Junginger et al., 2010). Despite the risk of being fecal incontinent, either in a monthly or daily episode, most patients would choose lower anterior resection rather than abdominoperineal resection (Bossema et al., 2008). Therefore, as the sphincter saving operation is the mainstream treatment, anterior resection syndrome would be increasing.

1.2 Affirming the Need

When the previously mentioned standard care fails to alleviate the bowel dysfunction problem, biofeedback (i.e. a noninvasive, painless and safe remedy) may be introduced and recommended to manage persistent fecal incontinence (Margolin, 2008). Biofeedback is a learning strategy originating from the psychological learning theories advocated by B. F. Skinner (P. Enck, Van der Voort, & Klosterhalfen, 2009). In essence of ‘instrumental learning’ and ‘operant conditioning’, if a human behavior is reinforced by intrinsic or extrinsic means, the likelihood of repeating that particular behavior would increase (P. Enck et al., 2009). Biofeedback is defined as the use of modern instrumentation to give better moment-to-moment information about a physical process under the control of the nervous system but not clearly or perceived (Miller, 1974). The use of biofeedback was started as early as 1974 and was used by Engel, Nikoomanesh, and Schuster (1974). The use of biofeedback in treating fecal incontinence since 1990s (P. Enck et al., 2009). Biofeedback uses visual signals to teach patients how to contract the external anal sphincter and how to use the pelvic floor muscles (Lundby & Duelund-Jakobsen, 2011). It aims to improve muscular strength of the external anal sphincter, improve rectal sensation and rectoanal coordination and to give the patients more consciousness of the pelvic floor (Lundby & Duelund-Jakobsen, 2011). During the biofeedback session, patient would exercise the external anal sphincter and the puborectalis muscle with a manometric probe. The probe is inserted into the anal canal and attached to a
visual or verbal amplifier that gives signals proportional to the pressure delivered by the external anal sphincter to the probe (Pucciani, Ringressi, Redditi, Masi, & Giani, 2008). Biofeedback helps to improve rectal sensitivity (Miner, Donnelly, & Read, 1990), increases the maximum squeeze pressure, duration of squeeze and maximum tolerated volume (Du et al., 2010; S. S. Rao, Welcher, & Happel, 1996) and decreases threshold volumes for first perception, rectal pressure and desire to defecate (S. S. Rao et al., 1996). These helps improve continence. Normally, individualized training programs last for 1–2 months and patients are encouraged to proceed the strengthening exercises lifelong (Lundby & Duelund-Jakobsen, 2011). Studies have shown that three weeks of biofeedback training can give statistically significant improvement in incontinence scores and the improvement can maintain for 1 to 2 years (Allgayer, Dietrich, Rohde, Koch, & Tuschhoff, 2005; Paul Enck, Däublin, Lübke, & Strohmeyer, 1994).

Biofeedback, due to its efficacy, the lack of side-effects, and scarce invasiveness, has been considered as an adequate approach for fecal incontinence (Chiarioni, Ferri, Morelli, Iantorno, & Bassotti, 2005). It is usually seen as appropriate if simple conservative measures such as dietary changes and antidiarrheal medication fail to restore continence (Christine Norton, 2010). In many reports, failure of biofeedback therapy to restore continence has been used as the criterion for consideration of progressing to surgical management for fecal incontinence (Christine Norton, 2010). This recommendation is based on the numerous positive outcomes from uncontrolled trials, limitations in the current RCTs and low morbidity associated with its application (C. Norton, Whitehead, Bliss, Harari, & Lang, 2010).

Having rectal cancer is already a tragedy. Despite the risk of being fecal incontinent, patients would prefer sphincter-saving operation that can preserve their body image from stoma formation and risk of postoperative mortality and morbidity. However, the anterior
resestion syndrome often fails with conservative medical management. The impact of fecal incontinence is devastating and can impair patients’ quality of life. Some of them even may need a stoma to regain the continence. This is, however, diametrically opposed to the aim of sphincter-saving operation. In view of this intractable fecal incontinence in this specific group of cancer survivors, biofeedback may be an option for this group because of the clinical effectiveness (Sloots, Bartlett, & Ho, 2009). In the current setting, fecal incontinence in postoperative patient is not well addressed. This causes patients to have an impaired quality of life, social isolation, dissatisfaction, and an impaired general well-being (Cassells & Watt, 2003; Parés et al., 2011; Philip & Miner, 2004; Rockwood et al., 2000; Verhagen & Lagro-Janssen, 2001; Wong, 1995). Healthcare professionals may also feel frustrated and perceive the resources are wasted (Deutekom et al., 2005). The image of the organization may also be depreciated. With biofeedback, patients may then be satisfied with less embarrassment, normal social functioning and avoiding stoma formation. Thus, this identified gap would lead to a discussion of whether biofeedback can ease the fecal incontinence problem for patients who have undergone rectal surgery. A systematic and scientific inquiry on the current evidence-based practice and comprehensive assessment and planning are needed to bring innovation to change the current practice.

1.3 Objectives and Significance

The objectives of the present study are:

- To gather evidences of biofeedback on improving intractable fecal incontinence after rectal surgery;
- To conduct a quality assessment of the identified studies and assemble evidences;
- To establish an evidence-based practice in the aspect of fecal incontinence;
- To establish implementation plan and evaluation plan.
With a systematic, detailed and scientific inquiry of the current evidences, the use of biofeedback may be promoted and more patients would be benefited from the evidence-based practice.

Chapter 2: Critical Appraisal

2.1 Search Strategies

2.1.1 Keywords for Searching Primary Studies

There are several groups of keywords used for searching research journals with references to the related topics from electronic databases. The first group of keywords related to intervention used, which included “biofeedback” and “biofeedback therapy”. The second group of keywords related to target-group patients used, which included “post-rectal surgery”, “fecal incontinence”, “rectal cancer”, “bowel dysfunction” and “anterior resection syndrome”. The third group of keywords related to outcome of intervention, which included “outcome”, “effects”, “short-term outcome” and “long-term outcome”. These keywords were used to search relevant research journals in five databases. They were MEDLINE (Ovid), MEDLINE (EBSCOhost), Cochrane Library, PubMed and CINAHL Plus. The databases were accessed via the Electronic Resources of the University of Hong Kong Libraries. The journal research was limited to non-review articles. The search results were limited to full-text journals, English written papers published from 1990 to current year. The research papers were selected with regard to the abstracts reviewed, and finally chosen within the inclusion criteria by manual selection. A table summarizing the research results, in brief, is shown in Appendix 1.

2.1.2 Inclusion and Exclusion Criteria

The studies in journal search included only if they are:
1. primary studies in English text in full-text,

2. published within the period from 1990 to current year,

3. either randomized controlled trials or pre-post experimental studies,

As the effect of biofeedback therapy on the fecal incontinence is our study focus, those reviewed journals or non-experimental studies would not be included in journal search. The subjects of studies suffering from fecal incontinence were selected, and they were limit to those had undergone colorectal surgery. The studies would use biofeedback as intervention to relieve its severity. The effects on fecal incontinence would be reviewed as outcome measures.

The studies in journal search exclude if they:

1. are non-primary or unpublished studies,

2. are written in non-English text,

3. are no full text available,

4. used children and geriatric groups as study subjects,

5. recruited patients with multiple sclerosis, spinal cord injury, idiopathic anal sphincter damage, pelvic floor dyssynergia and fistula.

6. recruited patients with history of abdominal trauma or obstetric trauma

In order to assess the outcome of biofeedback therapy on fecal incontinence, other means of interventions except biofeedback would not be considered. Also, there are studies included assessing outcome not only fecal incontinence, also evaluated the outcome on urinary
incontinence or other elimination disorders. These studies did not provide us significance of biofeedback on fecal incontinence, so they would be excluded in journal searching.

2.1.3 Method used for Data Extraction

In accordance with the inclusion and exclusion criteria, there were a total of five studies selected. The five studies emphasized on the outcomes of biofeedback on fecal incontinence, in which the study groups are not responsive to medical standard therapy or undergone post rectal surgery. Data on bibliographic citation, study design, participant characteristics, intervention, comparison, length of follow up, outcome measures, results and effect size and limitations from each study was tabulated. The data of those five studies was extracted as tables of evidence shown in Appendix 2.

2.2 Results

Based on the inclusion and exclusion criteria, a total of five studies were selected. The five selected studies focused on the outcomes of biofeedback on fecal incontinence. The study groups of these selected studies contained post rectal surgery and did not response to standard conservative therapy. Data on bibliographic citation, study design, participant characteristics, intervention, comparison, duration of the follow-up, outcome measures, results and effect size from each study was tabulated. Data of these five studies was extracted to form the table of evidence and is shown in Appendix 2.

2.2.1 The Identified Studies and Critical Quality Assessment of the Studies

A recent Korean study (Kim et al., 2011), a recent Australian study (Bartlett, Sloots, Nowak, & Ho, 2011) and a Singaporean study (Y. H. Ho, Chiang, Tan, & Low, 1996) were selected because their participants were highly relevant to the targeted population and intervention. The target population of these three studies was post colorectal surgery patients
failed to be treated with standard therapy. These three studies have a pre- and post-test design without a control group. The reason of having no control groups is because all of their participants were included into the interventions. In these three studies, participants’ progress were reviewed and assessed before and after the treatment. They completed the treatment from the initial session to the end of sessions. In addition, there are another two studies investigating on the effect of biofeedback on general fecal incontinence. One is a Spanish study (Lacima, Pera, Amador, Escaramis, & Pique, 2010) and another one is an American study (Heymen et al., 2009). There is no specific critical appraisal guideline developed by Public Health Resource Unit of the National Health Service in England or Scottish Intercollegiate Guidelines Network (SIGN) for pre- and post-test design. Because the selected studies were interventional studies, Critical Appraisal Skills Programme (CASP) on randomized controlled trials developed by Public Health Resource Unit of the National Health Service was used to appraise the studies. The CASP appraisal tool consists of 10 questions to evaluate the quality of the studies (Guyatt, Sackett, & Cook, 1993).

Of the three studies having a pre- and post-test design, their objectives were clearly stated (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011). Only Heymen et al. (2009) stated the research question clearly. In all selected studies, blinding the study personnel was not possible as they needed to be involved in providing the intervention in a specific schedule. Blinding participants of the study groups was neither possible. Only Y. H. Ho et al. (1996) mentioned that there was an independent investigator, whom was not associated with intervention but assessed the study outcome and progress. For the outcome measures, all data were collected prospectively and reviewed retrospectively. The changes of fecal incontinent episode and stool frequency were the major outcome measures. Selected studies used the Cleveland Clinic Florida fecal incontinence score and the number of bowel movements per day to evaluate the patients before and after the intervention. The instruments
used for data collection were identical in the three studies using the pre-and-post study design. The differences between the pre-intervention and the post-intervention were presented in these studies as the study outcomes. No power calculation was done among these studies. The change of fecal incontinence episode and the results were presented in the proportion format. Findings of physiological testing in anal manometry were also discussed among these studies but these results were not conclusive. Confidence interval were reported only in Bartlett et al. (2011). Two of the reviewed studies have a small sample size, 19 and 13 respectively (Bartlett et al., 2011; Y. H. Ho et al., 1996). The generalizability of the results of these two studies may thus be limited.

The Spanish study (Lacima et al., 2010) was a controlled trial without randomization and another American study is randomized controlled trial (Heymen et al., 2009). In Heymen et al.’s study (2009), the co-investigator generated a randomization table. The drop-out rate in Heymen et al. (2009) was 23% and the participation rate was clearly stated. Although, the dropout rate of those three pre-and-post design studies (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011) were not clearly mentioned, the threat to internal validity were explicitly examined and discussed. It highlighted the significance of randomization, which helps to minimize all the possible threats to internal validity. In Lacima et al.’s study (2009), the outcome measure was the episodes of fecal incontinence per year. It was calculated by multiplying the number of episodes of incontinence during the month after the intervention with the time interval of the follow-up. This method of calculation may introduce errors. Moreover, the self-reported satisfaction grading in this study was subjective measurement. The reliability and validity of the measurement is questionable. Lacima et al.’s study (2010) did not report a power calculation. Hence, the appropriateness of the sample size of their studies was questionable. Confidence intervals were reported in Lacima et al.’s study (2009). In Heymen et al.’s study (2009), the number of required participants was estimated to
adequately minimize the incidence of chance by power calculation. In two reviewed studies, quality of life inventory was used to evaluate the outcome (Bartlett et al., 2011; Heymen et al., 2009). Both studies had reported the p values and the standard deviations of the results wherever appropriate.

Among all reviewed studies, the results of intervention were reported to be positive and showed implications for future studies. However, the application of the results to other settings was not mentioned. The major limitation of Kim et al. (2011) was that not all of the participants in their study underwent regular anorectal manometry in the subsequent sessions. Kim et al. (2011) offered a preliminary suggestion for future prospective research in which more optimal intervention should be employed. Once the adequacy of sampling design has improved, the generalizability of results would be enhanced. Among the pre-and-post design studies (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011), patient’s history, maturation, mortality, testing and instrumentation change are the threats to internal validity (Polit & Beck, 2012). The threat of history included participants’ fatigue, post-operative recovery, or other bodily changes that may lead to an alternations on the study outcomes (Polit & Beck, 2012). For the controlled trial without randomization, the major threat to internal validity was the selection bias (Polit & Beck, 2012). In particular, the two study groups may not have similar background at the beginning of the study. The randomized controlled study can control all possible threats to internal validity.

In short, the level of evidence of the three pre-and-posttest design studies (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011) were rated at level III+, while the level of evidence of the other two controlled trials (Heymen et al., 2009; Lacima et al., 2010) were considered as level II.
2.3 Summary and Synthesis

The year of the publication of the selected studies ranges from 1996 to 2011 and their levels of evidence vary with respect to their research design. The three studies with pre- and post-test study design belong to level III (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011). The controlled study without randomization belongs to level II (Lacima et al., 2010) and the only randomized controlled trial also belongs to level II (Heymen et al., 2009).

The mean age of the participants in the reviewed studies ranged from 58.1 to 64.1 years old. All of the reviewed studies included postoperative patients and three of the studies specifically focused on patients who had undergone rectal surgery (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011). Among these three studies, participants were selected with anterior resection, total colectomy, low anterior resection, proctocolectomy with ileal pouch anal anastomosis done. The incontinence problem of the participants among these three studies lasted from 6 months to 12 months after the operation. In the other two studies, participants had symptoms persisted from four weeks (Heymen et al., 2009) to 41 months (Lacima et al., 2010). Before the biofeedback treatment, participants received diet modification (Bartlett et al., 2011; Lacima et al., 2010), anti-diarrheal medication (Bartlett et al., 2011; Y. H. Ho et al., 1996; Lacima et al., 2010) and home pelvic floor exercise (Bartlett et al., 2011). Among the three studies specific to the post rectal surgery patients, the time between the biofeedback treatment and the operation ranged from 18 to 27.9 month (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011). By synthesizing the findings from these studies, it seems that adult patients who had rectal resection surgery for 6 to 12 months and had fecal incontinence problem for at least four weeks post operatively and failed standard treatment can be benefited from biofeedback.
The biofeedback treatment utilized in the reviewed studies provided visual feedback by display (Y. H. Ho et al., 1996), computerized monitor (Bartlett et al., 2011; Heymen et al., 2009; Kim et al., 2011) or electromyogram (Kim et al., 2011). The sensors used for rectal pressure detection were manometric rectal balloon probe (Bartlett et al., 2011; Heymen et al., 2009; Y. H. Ho et al., 1996; Kim et al., 2011; Lacima et al., 2010). Clinical nurse specialist carried out the biofeedback treatment (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011; Lacima et al., 2010). The length of the follow-up ranged from 5 weeks to 3 months and the frequency of the follow-up was once in a week. Each session of the biofeedback treatment in all selected studies lasted for 45-60 minutes. The session interval across the selected studies was once in a week lasting for four weeks (Bartlett et al., 2011; Y. H. Ho et al., 1996), once in a week lasting for ten weeks (Kim et al., 2011), or biweekly for 12 weeks (Heymen et al., 2009). All of the studies encouraged patients to continue pelvic floor exercise at home (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011). The follow-up ranged from 5 weeks to 12 weeks and had an extended review ranged from 10.6 months (Y. H. Ho et al., 1996) to 2.4 years (Bartlett et al., 2011). Therefore, an effective biofeedback treatment requires a clinical nurse specialist to operate a manometric rectal probe that provides visual feedback. The treatment regime would be a one-hour session undertaking on a weekly basis for at least four weeks.

The outcomes were measured by assessing the subjective and objective data. The common outcome measures included incontinence episodes, fecal incontinence assessment tool, and quality of life inventory. In the reviewed studies, patients in the treatment groups were reported to have a statistically significant improvement in the measure outcomes after the treatment (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011) or their measure outcomes were found to be better than those in the control group (Heymen et al., 2009; Lacima et al., 2010). Anomanometry findings including maximal squeezing pressure,
maximal resting pressure, rectoanal inhibitory reflex and initial sensation were reported in all the selected studies except the Lacima et al.’s study (2010). No statistical significant difference on anomanometry was found in Bartlett et al.’s (2011) and Ho et al.’s (1996) study but Kim et al.’s (2011) study found there was improvement in squeezing pressure ($p=.006$) and rectal capacity ($p=.003$). And Heymen et al. (2009) also reported an improvement on squeeze pressure ($p=.014$) and lower abdominal muscle contraction ($p=.001$). Satisfaction level was assessed in three studies (Bartlett et al., 2011; Kim et al., 2011; Lacima et al., 2010). Bartlett et al. (2011) used a subjective bowel rating scale (a maximum of 10) and found the score increased from 3.3 in pre-test to 7.3 in post-test ($p=.006$). Kim et al. (2011) used VAS 1-100 scale (1 was extremely dissatisfied and 100 was extremely satisfied) and found the reported score was 61. Lacima et al. (2010) used a three-point scale to assess the satisfactory level and found that 91% of the participants rated better than before the treatment, 7.6% of the participants had unchanged score, and 1.3% reported a lower score than before the treatment. The percentage of participants reported a positive attitude towards the treatment in the treatment group was higher than the untreated group ($p<.001$). The overall incontinence episodes, quality of life and satisfaction score were improved after the biofeedback treatment.

The treatment effect not only lasts for a short period of time but also sustain for a long-term basis. All of the selected studies showed significant positive effect in a relative short period of time (5-12 weeks) and some showed persistent effect on a long-term follow-up, up to 2-3 years (Bartlett et al., 2011; Lacima et al., 2010). Two of the reviewed studies had a small sample size (Bartlett et al., 2011; Y. H. Ho et al., 1996) and three of them, due to their study design, are considered to have low level of evidence (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011). Findings of these studies have a limited generalizability. However, Heymen et al.’s randomized clinical trial (2009) and Lacima et al.’s controlled trial (2010) provided a higher level of evidence in supporting the beneficial effect of biofeedback.
treatment over the standard care with pelvic floor exercise. In addition, there was no complications reported and the satisfaction level was high among all studies. Therefore, with the above evidence supporting the short-term and the long-term positive effect of biofeedback and operational framework plus there was no report of negative effect, biofeedback can be helpful for those post rectal surgery patients with incontinence problem.

Chapter 3: Translation and Application

3.1 Implementation Potential

After critically appraised current evidences, biofeedback is helpful in improving persistent fecal incontinence after rectal surgery (Bartlett et al., 2011; Heymen et al., 2009; Y. H. Ho et al., 1996; Kim et al., 2011; Lacima et al., 2010). In order to put this innovation into practice, the implementation potential of biofeedback, including the transferability, feasibility, and the cost benefit ratio (Polit & Beck, 2012) will be addressed. The transferability will focus on the congruence of the innovation and the practical settings in terms of its philosophy, types of clients, personnel involved, financial and administrative structure (Polit & Beck, 2012). The feasibility will focus on practical concerns about the independent nature of the innovation, the availability of staff and resources, the organizational climate, the need for and availability of external assistance, and the potential for clinical evaluation. The cost-benefit ratio would analyze the costs, benefits and risks to clients, staff and the organization when implementing and not implementing the innovation (Polit & Beck, 2012). With this comprehensive assessment, problems in the practical setting can then be anticipated prior to implementation and corresponding improvement could be made in advance. Resistance to such innovation would be minimized and possibility of advancing care would be increased. Those factors affecting implementation potential will be discussed in the following sections.

3.1.1 Transferability
3.1.1.1 The proposed setting

The proposed setting is a regional hospital under the Hospital Authority which is a statutory body responsible for managing Hong Kong's public hospitals and their services to the community (Hospital Authority, 2010a). The philosophy of care of the proposed organization can be seen by its mission and value. The Hospital Authority has the mission of ‘Helping People Stay Healthy’ and its value is ‘People centered care’ (Hospital Authority, 2010a). It has a position statement on holistic care which stresses person is viewed with dignity and value (Hospital Authority, 2000). Holistic care nursing should be updated and justified with reference to evidence-based practice (Hospital Authority, 2000). Therefore, this shows the organization would support current evidence based innovation in the aspect of its philosophy of care.

The proposed setting will be one of the largest acute regional hospitals in Hong Kong. It is also the teaching hospital of The University of Hong Kong (Hospital Authority, 2010a). It serves 0.55 million populations in the region but the actual number would be significantly larger because of cross cluster flow of clients (Hospital Authority, 2010b). The mission of the hospital is to provide patient-centered high quality service to the community in an effective and efficient manner by optimum utilization of available resources, through the concerted efforts of satisfying patients' needs, facilitating staff's motivation and inviting public participation; to provide the highest quality of patient-centered service possible to the people of Hong Kong with empathy, expertise and excellence. The nursing philosophy of the hospital is that, ‘Nursing is a helping and caring service involving collaboration among nurses, patients and their significant others’ and ‘Nurses are accountable for their nursing practice that promotes and/or restores the well-being of patients, families, other social groups and the community as a whole’ is exhibited on the notice board (Queen Mary Hospital, 1996).
Therefore, the philosophy of care of the hospital is in line with the current innovation which can not only improve fecal incontinence, but also promote self-esteem, rehabilitation, social functioning and minimize dissatisfaction.

The proposed setting would be out-patient setting which is the same as the selected studies. There are around 500 adults having elective colorectal cancer surgery cases per year in the hospital. Based on the postulation that 60% have cancer of rectum (Li & Gu, 2005; Xu et al., 2010), about 300 cases is postulated to undergo operation for rectal cancer. From some studies, the incidence of fecal incontinence after rectal surgery was from 16%-60% (P. Ho, Law, Chan, Lam, & Chu, 2003; Taylor & Morgan, 2011). By taking the mean prevalence as 38%, there will be around 110 patients having fecal incontinence after rectal surgery per year in the proposed setting. Therefore, it is believed that there is a significant number of patients benefiting from this innovation per year. The biofeedback treatment would last for four weeks with significantly improved effect and its evaluation could then be made.

3.1.1.2 The proposed audience

The proposed audience would be motivated Chinese patients, who age over 18, after rectal surgery without temporary or permanent stoma that experience persistent fecal incontinence despite dietary modification and medication for 6-12 months. This is the same target group of patients who are going to benefit from biofeedback treatment. The evidence of the innovation came from Americans (Heymen et al., 2009), Korean (Kim et al., 2011), Australian (Bartlett et al., 2011), Singaporean (Y. H. Ho et al., 1996) and Spaniard (Lacima et al., 2010). However, the proposed audience would be Chinese. When considering the transferability of biofeedback from the selected studies, related studies on Chinese population were sought. Some studies showed that biofeedback was also effective in managing fecal incontinence in similar Chinese population (Du et al., 2010; Xie, Jin, & Chen, 2005; 郑 et
al., 2009). These studies were excluded under the exclusion criteria as they were reported in Chinese or no full text available and used for consideration of transferring biofeedback into Chinese population. Therefore, the biofeedback therapy could fit into the proposed setting and audience.

3.1.2 Feasibility

There are several components in the biofeedback treatment; namely, a rectal probe with balloon protected with plastic sheath, the machine, the exercise regime most commonly one hour session per week and a trained biofeedback therapist.

3.1.2.1 Resources related aspect

The resources and equipment required include a biofeedback machine, a rectal probe, some disposables and a silent private room. For the biofeedback machine, it is not available in the surgical department but there is one owned by pediatric department. Therefore, the machine could be shared among different departments for better resources usage and services expansion without incurring extra cost. The rectal probe, which is reusable, could be purchased via procurement department. Disposable plastic sheath covering rectal probe costs about HKD$0.5 each. In addition, a private room for the nurse clinic session is needed, for example, an out-patient clinic room which is silent enough to prevent distraction on the visual or audio feedback.

3.1.2.2 Operator-related aspect

Enterostomal therapists are registered nurses who have passed a certificate program on stoma, wound and continence care recognized by the World Council of Enterostomal Therapists (HKU SPACE, 2010). This 9-month part-time program consists of theoretical input and practicum, including biofeedback training. There are about 50 enterostomal
therapists in the proposed setting, who have minimally 7 years of clinical experience. They were sponsored by the surgical department for the enterostomal therapist training and could be deployed from their clinical duties. In order to provide seamless services, at least two qualified nurses from in-service units would be coached. There will be in-house training and rotation of staff in order to maintain sustainability and increase staff exposure to biofeedback.

3.1.2.3 Nurse related aspect

Seeking frontline staff support is crucial as the change requires effort, retraining and restructuring of work habits (Polit & Beck, 2012). Evidences and effects of the innovation will be shared with the potential operators and clinic nurses in order to increase the understanding and acceptance. For the arrangement of the equipment and space by the clinic staff, minimal extra workload will be added and ownership will be provided. In addition, introducing this innovation could lead to professionalization and expanded nursing roles. This enhances nurses’ job satisfaction. However, some frictions would be expected from other departments which provide similar treatment to the similar patient groups, for instance, physiotherapist may provide pelvic floor exercise to urinary incontinence women and biofeedback to general constipation patients. Confusion on triaging the patients might be one major concern. As the surgeons work closely with the enterostomal therapists not only in inpatient settings but also out-patient settings, it is easier for enterostomal therapists to promote the innovations and make referral within the department by the surgeons.

3.1.2.4 Nursing profession related

In Hong Kong, biofeedback is usually carried out by qualified nurses. It is included in specialty nurse training curriculum, for example, enterostomal therapist or continence nurse, in Hong Kong. Their qualification would be recognized in the Hospital Authority after meeting certain requirement. Therefore, they could have freedom to initiate and terminate the
treatment within the organization. There are also nurses clinic on continence operating in Hong Kong. The referral can be made by doctor, nurses, enterostomal therapist and colorectal nurse specialist. There will be a need in communicating among the health care teams, which can be done by progress notes in the computerized patient record.

### 3.1.2.5 Organizational related aspect

The nurse authority to implement and document in the computerized record should be sought. There were several nurse clinics, namely stoma care, wound clinic and urological nurse specialist clinic, in the proposed hospital. This showed tremendous support from administrators, including Divisional Chief of Service, who supports the research utilization and improvement on nursing practice; Departmental operation manager, who supports nursing development, innovation and nursing professional development. The surgical department operation manager actively supports continue nursing education with sponsorship, official release and study leave for different training courses and conferences which can improve or expand nursing practice. The nursing staff is also encouraged in conducting researches and presenting in international congress with different funding available. The financial support could be sought from the budget holder of the department who supports the use of evidence-based practice. This showed the climate on promoting changes, innovations and evidence-based practice is good.

### 3.1.2.6 Evaluation

The evaluation of the effectiveness of biofeedback will be based on Fecal Incontinence Quality of Life Scale (FIQL) (Rockwood et al., 2000) (Appendix 5), Fecal Incontinence Severity Index (Rockwood et al., 1999) (Appendix 6), Pelvic floor muscle strength by Oxford Scale (Laycock, 1994), patient bowel diary (S. S. C. Rao, 2004) with the help of diagrammatic Bristol stool scale (S. J. Lewis & Heaton, 1997) (Appendix 7) and anal
manometry. Those questionnaires can be retrieved from the Internet. Anal manometry is currently available in the proposed setting and is done by nurse specialist.

### 3.1.3 Cost benefit ratio of the innovation

#### 3.1.3.1 Potential benefit

Biofeedback treats about 67% for functional fecal incontinence (Palsson, Heymen, & Whitehead, 2004). The continence episodes could significantly reduced from 2.7 per day to 0.4 per day (Y. H. Ho et al., 1996), 1 per week to 0.5 per week (Kim et al., 2011) and 23% more archiving complete continence (Heymen et al., 2009; Lacima et al., 2010). In other words, the use of pad and incontinence products, which is costly (Brazzelli, Shirran, & Vale, 2002), could be reduced. The number of antidiarrheal agents reduced from 6 to 2 (Y. H. Ho et al., 1996). The efficacy could sustain 6-12 months (Heymen et al., 2009; Lacima et al., 2010; Ryn, Morren, Hallböök, & Sjödahl, 2000). As the innovation could improve the patient fecal incontinence problem with long-term effect, patient dissatisfaction would be improved. There will be more autonomy and expanded nursing role that could promote job satisfaction.

Keeping current practice could not meet patients’ expectation, impair patients’ social life, and sustain low self-esteem and embarrassment. Some of them with intractable fecal incontinence may even need to create a permanent stoma. Due to the aforementioned unaccomplished complaints, staff morale and job satisfaction will be damaged and the organizational image would be poor.

#### 3.1.3.2 Potential risks

There was no physical risk reported from the selected studies. Lam and Kwok (2001), who are Hong Kong specialist surgeons, had an opinion that biofeedback is a helpful adjunct carrying no risk in its own right. There will be few discomfort expected during the insertion
of the rectal probe. It should be tolerable but informed in advance with counseling. However, there may be psychological risk that biofeedback is the last resort to them and would lead to anxiety and biased report on incontinence improvement. It is the responsibility of operator to clearly explain the treatment and related concerned issue to the patient. An information pamphlet on how biofeedback works, the course of biofeedback and related home care would be given to patients.

3.1.3.3 Cost of fecal incontinence

There were very few data available on the direct costs of treatment for fecal incontinence. This is because most affected individuals do not seek health care (Philip & Miner, 2004) and the cost of diagnostic tests were not considered. The large-volume fecal incontinence reported missing an average of 50 days from work or school in the past year (Drossman et al., 1993). One British study found a 4-fold increase in anxiety and a 5-fold increase in depression (Edwards & Jones, 2001). Another Dutch study reported anxiety, shame, and frustration (Verhagen & Lagro-Janssen, 2001). The impact of incontinence on older spousal caregivers includes role change, financial cost, decreased intimacy, emotional responses, sleeping issues and social isolation (Cassells & Watt, 2003).

Monetary costs to the individual may arise from increased laundering, purchasing new clothes, purchasing pads or over-the-counter medications and inability to work (Hurnauth, 2011). Costs to the primary care service include the provision of medication, equipment and consultations (Hurnauth, 2011). One Dutch study estimated total cost for fecal incontinence is €2169 per fecal incontinent patient per year with more than half of these costs were indirect non-medical costs associated with help needed by unpaid activities than by impact on paid activities (Deutekom et al., 2005).

3.1.3.4 Estimated monetary cost
When calculating the monetary cost, manpower, resources and consumables should be considered. The whole treatment consists of 5 one-hour sessions. Each session requires one plastic sheath (HKD$0.5 each), one hour of 7-year experience staff nursing time (HKD$170 per hour). The indirect cost to the patient would be HKD$100 on first attendance and HKD $60 subsequently per visit (Queen Mary Hospital, 2003). The training of operator would be the on job training that provided by the nurse specialist. The silent private room will be on hospital premise. A course of treatment costs around $1192.5 and expecting would have decreased incontinence episodes over 1 year.

3.1.3.5 Estimated benefit

The incontinences episodes could reduce from 2.7 to 0.4 per day (Y. H. Ho et al., 1996) or 1 to 0.5 times per week (Heymen et al., 2009; Kim et al., 2011). In view of this large variance, one episode of fecal incontinence is assumed to prevent every two days after introducing the biofeedback. And expecting the effect of biofeedback could last for 12 months (Heymen et al., 2009; Lacima et al., 2010; Ryn et al., 2000), the duration will be calculated by using one year time. Each disposable incontinence pad costs about HKD$8 per piece. If there is one pad reduction every two days, the cost saving will be HKD$1460 per year. In addition, there is expecting the decrease the use of antidiarrheal. The cost of daily antidiarrheal is about HKD $0.34 per day and that means one year cost would be HKD$124.1. If there is a reduction in half usage, HKD$62.05 is saved. Therefore, estimating HKD$1522.05 will be saved per year. In addition, other related indirect non-medical cost and unpaid activities are not calculated but expected to be decreased.

Biofeedback carries the lowest cost in managing rebellious fecal incontinence when comparing with other surgical intervention and the success is usually evident after 3–6 treatment sessions. If the treatment is successful, it is also durable, with few patients requiring
additional treatment (Philip B, 2004). When calculating the cost over benefit on monetary basis, it is worthwhile to carry out. If the opportunity costs, like psychological and social impacts, are considered, it is more justified to introduce biofeedback into practice. Biofeedback is of extreme low risk and lots of benefits, not only to client, nurse and even the organizational image. It is transferable, feasible to implement in the proposed settings. Therefore, develop a protocol is worthwhile to put it into practice in a user-friendly way.

3.2 Evidence-Based Practice Protocol

An evidence-based clinical practice protocol for the proposed program was developed to help standardizing the practice of the nurses concerned. This provides guidance on assisting professionals to set up and to implement interventions. The protocol is employed to assist the nurses concerned using the biofeedback for the post rectal surgery patients with fecal incontinence. The objectives of the protocol are to address concerns for those patients suffering from fecal incontinence. Also, it has been developed to standardize the practice, so that better well-being and self-esteem of our target groups would be promoted. The target groups are the patients after rectal surgery with at least 6 months apart. Their bowel dysfunction on incontinent episodes failed to be alleviated with standard care such as medication and dietary modification. The target subjects are adults with at least one episode of fecal incontinence per week, communicable, self-motivated and cognitively intact. They need to do pre-study assessments to exclude structural and metabolic disorders. The patients with known history of perineal trauma and anatomical defects are excluded. The outcome to be evaluated would be the number of episodes in incontinence, post treatment satisfaction scores, use of incontinence pads and the perception in social functioning. The following recommendations are rated the level of evidence and graded by Scottish Intercollegiate Guidelines Network (SIGN) (Appendix 9).
Clinical Protocol

Recommendation 1.0

The patients with fecal incontinence for more than 6 months despite dietary modification and medical treatment should be recruited.

The fecal incontinence brings negative impact on person’s quality of life. The patients had failed to respond the conservative treatment by dietary or medication methods could be treated by biofeedback therapy as alternatives (Heymen et al., 2009; Lacima et al., 2010) (2+) (Bartlett et al., 2011; Y. H. Ho et al., 1996) (3+).

Grade of recommendation: B

Recommendation 1.1

The post-rectal surgery patient with fecal incontinence may begin treatment 18 or more months after surgery

The biofeedback therapy was tested to be effective on the group of patients after surgery. The post-surgery patients who started the treatment 18 or more months after surgery had better scores on the fecal incontinence and number of bowel movements (Kim et al., 2011) (3+). The authors also suggest delaying the start of program might enhance its effectiveness, whereas it takes time for one to adapt to postoperative changes (Kim et al., 2011).

Grade of recommendation: D

Recommendation 2.0

A symptom questionnaire with physical examination should be conducted to have a thorough assessment of each patient before the start of the therapy sessions
A questionnaire was given to each patient to record his own bowel habit and severity of fecal incontinence. The initial physical examination was recommended to carry out to confirm no surgically correctable lesions (Lacima et al., 2010)(2+). It was also conducted for the study patients to list the impact of fecal incontinence on their quality of life (Bartlett et al., 2011)(3+). The background of the patients needs to be considered whereas the training needs high degree of collaboration in daily home practice.

Grade of recommendation: C

**Recommendation 3.0**

*Instrument-assisted biofeedback is an essential element of successful training*

Biofeedback therapy consists of pelvic floor muscle strengthening exercises and visual feedback training (Ozturk, Niazi, Stessman, & Rao, 2004). The therapy is performed by placing an anal probe with a rectal balloon and pressure transducer (Heymen et al., 2009; Lacima et al., 2010)(2+) (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011)(3+).

<table>
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<tr>
<th>Types</th>
<th>Uses</th>
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<tr>
<td>Visual feedback on monitor</td>
<td>The patients needed to observe the anal and rectal pressure changes on a monitor (Y. H. Ho et al., 1996; Kim et al., 2011)(3+)</td>
</tr>
<tr>
<td></td>
<td>The anal pressure changes as indicated to patients’ efforts to contract and relax the anal sphincter muscles. (Y. H. Ho et al., 1996) (3+)</td>
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</table>
Computer assisted visual feedback

The patients watched the computer monitor showing the anal and intrarectal pressure changes presented as ling graphs (Heymen et al., 2009)(2+) (Bartlett et al., 2011)(3+).

The instrument-assisted feedback with the use of solid-state anorectal manometry probe helps the patients in training on either improving anal sphincter strength or muscles coordination and its sensation.

Grade of recommendation: B

Recommendation 4.0

*45 minutes to 1-hour training session of biofeedback therapy with individualized frequency of sessions should be designed.*

In each session, there are three maneuvers including strength training on anal sphincter, sensory training and coordination training (Heymen et al., 2009; Lacima et al., 2010)(2+) (Ozturk et al., 2004).

<table>
<thead>
<tr>
<th>Training sessions</th>
<th>Description</th>
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| Strength training in anal sphincter and pelvic floor muscles | 1. Stay in left lateral position and flex hips to 90 degrees  
2. Instruct to squeeze and maintain its pressure as long as possible,  
3. Instruct to avoid using abdominal wall muscle |
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<td></td>
<td>4. Ask for home practice between sessions (10-20 minutes per day, at least 20 squeezes per session)</td>
</tr>
</tbody>
</table>
| Sensory training | 1. Increase rectal balloon by 20-30ml each time to induce sensation of urge to defecate  
                           2. Recognize sequentially smaller volumes of distention  
                           3. Establish a new sensory threshold |
| Coordination training | 1. Educate the patient to squeeze voluntarily in response to rectal distention  
                                  2. Train the voluntary contraction of the sphincter muscles. |

The frequency might be varied from once weekly for four weeks (Y. H. Ho et al., 1996)(3+) to twice weekly for six times (Heymen et al., 2009)(2+). The numbers of training sessions are five on average, and customized for each patient according to their own needs.

Grade of recommendation: B

**Recommendation 5.0**

*Each target patient need to be instructed to continue pelvic floor exercise at home as prerequisite*
All the studies reviewed emphasized that the patients need to do pelvic floor exercise at home (Heymen et al., 2009; Lacima et al., 2010)(2+) (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011)(3+). The patients were taught to squeeze muscles without biofeedback equipment at home. This self-motivated home exercise regimen needs to be highly appreciated so that a better outcome of therapy would be resulted.

Grade of recommendation: C

**Recommendation 6.0**

*Dietary modification, medications and standard advices are needed to continue with biofeedback therapy*

The patients having biofeedback therapy are needed to record their food intake, medications used in the stool diary. They are advised to continue their usual medications and dietary modification during the therapy (Bartlett et al., 2011) (3+). The patients were allowed to continue their antidiarrheal agents and to titrate its dosage based on symptoms (Ozturk et al., 2004). Standard advice regarding fluids, fiber, feet position during defecation, and fitness were needed to give to all patients receiving biofeedback training (Heymen et al., 2009) (2+).

Grade of recommendation: C

**Recommendation 7.0**

*The biofeedback training sessions should be implemented to the patients individually with periodic reinforcements.*

An individualized training session can provide support tailored to a patient’s needs and barriers. The number of sessions could be customized to the patient’s need, though the average number of sessions is about five. Additional sessions would be provided in selected
cases (Lacima et al., 2010)(2+). It should be emphasized that continuing exercise and periodic reinforcement could prevent expected worsening over time (Pager, Solomon, Rex, & Roberts, 2002; S. S. Rao et al., 1996). The biofeedback program demonstrated sustained improvements, mainly due to the use of periodic reinforcements during the therapy (Ozturk et al., 2004).

Grade of recommendation: C

**Recommendation 8.0**

*Subsequent follow up are needed to evaluate the outcomes*

A three-month follow up evaluation was done regardless of changes in fecal incontinence episodes. During follow up session, severity of fecal incontinence after treatment would be assessed (Heymen et al., 2009)(2+). Functional improvements have been demonstrated for a mean of 11 months after treatment. (Y. H. Ho et al., 1996)(3+). Anorectal manometry was repeated before or after the treatment sessions (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011) (3+). The efficacy of biofeedback therapy was evaluated by pre and post testing results.

Grade of recommendation: C

**Recommendation 9.0**

*A symptom diary should be provided to assess the efficacy of biofeedback therapy and its effect over time*

A symptom diary for each patient should be provided to record the stool type, its frequency and consistency, food intake and anti-diarrheal medication (Heymen et al., 2009)(2+) (Bartlett et al., 2011; Y. H. Ho et al., 1996; Kim et al., 2011)( 3+). Each subsequent follow up session would review the patient’s diary and check the patient’s progress. The
efficacy of biofeedback over a period of time ranged from 1 month to 60 months would be assessed with the use of diary (Lacima et al., 2010)(2+). The subjective rating on satisfaction with fecal incontinence was also reviewed in the stool diary.

Grade of recommendation: B

**Recommendation 10.0**

*The biofeedback training session should be implemented by trained specialist.*

The general knowledge on anatomy and physiology of the anorectum and functional abnormalities shown in anal manometry should be delivered to patients by a trained nurse (Lacima et al., 2010)(2+). Two trained clinical nurse therapist were involved in training delivery, which includes the following three maneuvers: strength, sensory and coordination training (Kim et al., 2011)(3+). The trained and qualified specialists have knowledge in stoma therapy and continence nursing. For the health education, the therapist gave advice on coping strategies, medications and dietary choice (Bartlett et al., 2011)(3+). The standardized assessment on physiology testing outcomes and following evaluation of the impact on the fecal incontinence could be achieved and sustained.

Grade of recommendation: C

**Recommendation 11.0**

*The psychological needs and satisfaction on the therapy of the patients should be addressed and evaluated*

Apart from anorectal function assessments done pre and post the training sessions, the patients’ self-rating scores on quality of life are also analyzed. Patients had reported the significant change in lifestyle and embarrassment in social functioning with reference to Fecal
Incontinence Quality of Life (FIQL) (Rockwood et al., 2000) as shown in Appendix 5 (Bartlett et al., 2011) (3+). The subjective assessment data of the patients was also illustrated and analyzed (Lacima et al., 2010)(2+). The subjective satisfaction scores with bowel function before and after the treatment were also evaluated using visual analog scale (Kim et al., 2011)(3+). The subjective assessment of the patients on biofeedback therapy was also important so as to evaluate the efficacy of biofeedback in a long run.

Grade of recommendation: C

After a detailed, sophisticated review of current evidences, biofeedback in an outpatient clinic setting carried out by enterostomal therapist could improve fecal incontinence, quality of life and satisfaction of the clients (Bartlett et al., 2011; Heymen et al., 2009; Y. H. Ho et al., 1996; Kim et al., 2011; Lacima et al., 2010). Also, after cost-benefit calculation, it is cost effective without foreseeable harm to the patient. After the evidence-based protocol established, implementation, communication and evaluation plan would be necessary to elicit and tackle foreseeable difficulties and to receive approval from the organization.

**Chapter 4: Implementation Plan**

Referring to a model could give a framework how to make changes on current practice. The proposed change would adopt the Lewin’s change model (Lewin, 1947). Lewin’s change model consists of three steps, namely unfreezing, moving and freezing. Lewin (1947) postulated that inertia in the form of a quasi-stationary equilibrium is the main obstacle to change (Schein, 1996). A planned intentional change is needed to break the equilibrium and transit to a newly created equilibrium (Weick & Quinn, 1999). Lewin (1947) suggested that an equilibrium would be changed more easily if restraining forces such as personal defenses, group norms, or organizational culture are minimized. Unfreezing could
involve three processes: (1) disconfirmation of expectations, (2) induction of learning anxiety if the disconfirming data are accepted as valid and relevant, and (3) provision of psychological safety that converts anxiety into motivation to change (Schein, 1996). People will be motivated to learn something new and attentive to ideas that are in circulation when unfreezing occurs (Weick & Quinn, 1999). Therefore, a change agent who could establish conditions and circumstances as mentioned in above using a series of actions either in collaboration with other people or singularly could help to make an intentional change (Ford & Ford, 1995). After the change, refreezing is essential to make the new behavior sustainable and prevent the relapse of old behavior. It is most likely to occur when the behavior fits both the personality of the target and the relational expectations of the target’s social network (Weick & Quinn, 1999). An implementation plan incorporated with a communication plan targets on motivating the change was established to unfreeze the current practice.

4.1 Communication Plan

It is essential to obtain support from the stakeholders to make the changes occur. The stakeholders are defined by Clarkson (1995) as “persons or groups that have, or claim, ownership, rights, or interests in a corporation and its activities, past, present, or future” (p.106). Ackermann and Eden (2011) clearly stated that: “paying attention to managing a specific set of stakeholders will have a powerful effect on achieving strategic goals and long-term viability” (p.181). Those involved in the implementation of the innovation would be elicited as stakeholders. In the current situation, Chief of Service, Residents, Departmental Operation Manager (DOM), Ward Managers, Advanced Practice Nurses (APN), Clerks, Specialty Out Patient Clinic Nurses and Enterostomal Therapists are identified as stakeholders for implementing the biofeedback protocol. The Chief of Service, DOM and ward manager are the administrators who determine the approval of the proposed plan. The
APN acts as a leader to support and execute the proposed plan, whereas specialist out-patient clinic nurse and clerks would facilitate the logistics of the approved proposal.

The levels of interest and power of the stakeholders should be assessed (Brugha & Varvasovszky, 2000) and they can be divided into four groups accordingly. Those with high power and high interest are ‘Players’, who are significant stakeholders and they deserve sustained management attention because they have high power to support the change (Ackermann & Eden, 2011). Residents, ward managers and advanced practice nurses would fall into this category. Those with high power but low interest are ‘Context Setters’, who can influence the overall future context and effort should be paid to raise their awareness and develop their positive attitude towards the proposed change (Ackermann & Eden, 2011). The higher management level, including the Chief of Service and Departmental Operation Manager would fall into this category. For individuals with low power but high interest, they are ‘Subjects’ and they should be encouraged coalitions to increase power of positive or neutralize the negative (Ackermann & Eden, 2011). The operator of this innovation, that is the enterostomal therapists, would fall into this category. The last category, the low power and the low interest people, are referred as ‘Crowd’ and they could be seen as potential stakeholders who are unlikely to be worth management time or effort (Ackermann & Eden, 2011). The specialist out-patient clinic nurses and clerks fall into these categories and they would be adequately informed and talks would be given to them in order to ensure no major issues would arise.

According to this framework, a tailor made communication plan for different groups of stakeholders was designed. A compelling message could initiate the unfreezing process and such message could be delivered by providing the current practice problem, the evidences of how and why the intentional change is necessary and what can be accomplished. Reasons of
resistance may include uncertainty, concern over personal loss, or the belief of the change is not of the organization’s best interest (Robbins & Coulter, 2002). Robbins and Coulter (2002) suggested that education and communication, participation and facilitation and support could reduce some of the resistance. Frooman (1999) suggested understanding what stakeholders want and how they can work towards achieving it can help define possible management actions (Ackermann & Eden, 2011). Talking to the stakeholder would be the most direct method in assessing their needs. But, by analyzing their position, there may be some clues showing their interest. For the Chief of Service, they are budget holders and they will focus on resource allocation, organization effectiveness, as well as the image of the department. For DOM, they not only focus on the expenses and the department image but they are also interested in the manpower planning and professional development of nursing staffs. For ward managers who have to monitor the quality of patient care, they are interested in both clinical needs in the specialty and the professional development. The staff deployment is also a concern of the ward manager as manpower and resource utilization for the new project would affect the staffs’ routine practice and working days. For the advanced practice nurses, their interests are relatively in service planning, implementation, and evaluation. They focus on the clinical care pathway and manage nurse-led services. With their specialist role in the clinical specialty, they would estimate the feasibility of the proposed plan, the resource needed and its allocation related to the change and the predicted difficulties. For clinical specialist outpatient clinic nurse, they would consider the healthcare delivery for the patients and their family and the coordination across different disciplines. With vigilant on their interests, different approaches would be used to convince them for implementing the new protocol.

The ‘Player’ group of the stakeholders (i.e. the specialty nurses and ward managers) would be approached first. For the specialty nurses, they may lead and supervise a nursing team within a clinical unit. They are responsible for initiating and participating in the
evidence-based practice in the clinical setting. They act as a resource person and referral agent on clinical expertise. The significance of the existing problems of the current practice in colorectal unit and its clinical needs would be highlighted. To enhance the feasibility of the proposed plan, staff deployment plan will be discussed with ward managers. Both the specialty nurses and ward managers will be informed with the evidence based protocol and the supportive evidences from the literature. The potential risks and benefits, cost-benefit ratio of the plan, inclusion criteria of the clients, the resources used in the study, the steps to implement the plan (Appendix 4) will be illustrated. They will be invited to provide their constructive feedbacks and comments for refining the proposed protocol and the implementation plan. The best way to communicate with those at middle management level is to give them a briefing prior to the study and to prepare written protocol for them to follow whereas any questions arise.

After convincing the ‘Players’, the ‘Context Setters’ would then be approached as they also have high power. The Chief of Service and Departmental Operative Manager belong to this higher management level. To ensure that they are satisfied with the proposed plan, a clear presentation of the proposed plan should be provided to them. However, as they may not have time for a verbal briefing of the proposed plan, the change agent would communicate with them using a written proposal. The written proposal should stress on the cost effectiveness and cost benefit ratio, and its expected outcome.

When the ‘Players’ and the ‘Context Setters’ are satisfied, the proposal would be allowed to implement. Then, the ‘Subjects’ would be approached. As the operator, the enterostomal therapists would play the most significant role. With the evidence-based clinical protocol, the enterostomal therapists would be convinced and required to follow the protocol.
The details of the protocol, subsequent training and coaching would be provided to them. Sharing from their hands-on experience is crucial for the evaluation of the new project.

The ‘Crowd’, that is the specialist out-patient clinic nurses and clerks who have low power and low interest, would then be informed. In order to implement the plan smoothly, clear goals of the proposed plan would be clearly illustrated. Information such as the workflow of the referral of the clients to the study, and the arrangement of the appointments is needed to be clearly mentioned. Flowchart with clear instructions will be provided for troubleshooting. The clerks are responsible for the non-clinical duties such as supplies stock and related stores duties. The general administrative works of the proposed plan such as the appointments arrangements have to be discussed with them.

After comments are received from the stakeholders, modification of the protocol would be made. The stakeholders would be invited for a briefing on the significance of the problems in the current practice, the goals and its necessities of change, the foreseeable advantages, its effectiveness and its potential risks. Further refinement would be made according to the audience’s feedbacks. The final approval of the proposed plan would be obtained from the administrators, including Chief of Service and Departmental Operation Manager. A pilot study would then be carried out after the coaching is done with the operators.

4.2 Pilot Study Plan

4.2.1 Aim

The aim of pilot testing is to test the work flow before the full implementation. It aims to check the feasibility of the innovation to see whether it is realistic and workable. In addition, the pilot study can help to identify actual problems and in turn can to develop strategies to
tackle or eliminate the problems accordingly. This allow the program to make corrective changes or adjustment (Lancaster, Dodd, & Williamson, 2004).

4.2.2 Methodology

The pilot test would be carried out on 5 clients from the targeted population. These 5 cases will be followed since the referral procedure starts till the whole program ends. The setting would be the same specialist out-patient clinic as designed. Data will be collected from the one-to-one interview conducted by the referrer, operator or the liaising staff. One responsible person from each party, including specialist out-patient clinic nurse, clerk, medical officer and operator would be interviewed for comments and improvements. Also, the whole process would be supervised for technical and logistic problems by nurse specialist. Since it is expected to have 8 news cases per month in the target setting, the estimated time frame for the pilot study would be one month. During the pilot study, the recruitment approach adequacy will be checked by the number of referrals and the first appointment date from the referral date. The logistic problem would also be addressed from comments from the clinical staffs and patients. Specifically, during the interviews with the operators, comments for the skills in carrying out the treatment would be elicited and the time required in each session would be recorded. In addition, the interview would elicit comments on whether the directions and instructions are clear enough; any misleading words or sensitive, difficult or unnecessary questions; needs of rephrasing or any problem in completing the assessment and evaluation tools.

4.2.3 Evaluation

After performing the pilot test, subsequent follow up with modifications would be made. The lost cases and streamlined care would be focused when dealing with the aspect of recruitment procedure. The instruments would be reviewed to see whether the corresponding
results are appropriate or matching the intended response. The difficulties reported from the frontline staffs would be addressed. And the findings would be shared with the stakeholders for further comments. Modifications would be made accordingly.

During the change, guidance would be provided. The referrers, operators and liaising staff would be communicated frequently on any difficulties, benefits or doubts. If problems are identified, it would be tackled immediately. They would be contacted once per week after each session and whenever it is needed. There is an ongoing assessment form to monitor the progress. Resource manual would be provided to tackle the expected problems. Once the change has been made, refreezing the change is the third step. Sustaining the change could be done by identifying the barriers and benefits and revising the protocol accordingly. Also, recruiting qualified staff can help to maintain the sustainability of the proposed change. The outcome could be evaluated by statistics, interviews and audit charts (Appendix 9). The success could then be shared to the Hospital Authority Convention or conferences and published in journals. Funding may be sought to maintain the practice. Therefore, an evaluation plan is needed to measure the outcomes.

4.3 Evaluation Plan

An evaluation plan could help to assess the effectiveness of the protocol, identify problems and constraints, assess satisfaction, address costs, and make modifications for the future implementation. From the literature, the range of sample size of the reviewed studies ranges from 13-168. Since no actual effect size of such intervention has been reported before, a medium effect size is predicted. The sample size calculation is based on a 5% significance level \((p < 0.05)\) and a power of 0.80 with an effect size of 0.5. Using these criteria, the number of clients to be recruited in this proposed study is expected to be 23 by paired t-test \(\text{Lenth}, 2009\). As attrition is common in studies with experimental design, we allow for the
potential attrition at a rate of 15% and therefore four more cases are needed (Polit & Beck, 2012). The yearly cases are expected to be about ninety-four. Therefore, the time frame for collecting data from the 27 cases would be around 4 months. However, it may be achieved earlier due to the existing cases before the project is carried out.

For assessing the patient outcome, some criteria should be met before taking the data into analysis. The patients should be complied with the protocol in which they should have completed the treatment course and followed the home advice. The primary outcome to be measured is the reduction of the incontinence episodes, which are the foremost important shortcomings of the fecal incontinent patients. The patients would be evaluated by the bowel diary (S. S. C. Rao, 2004)(Appendix 7) describing the incontinence episodes in one month after the participation. From the literature, the effect of time in influencing the outcome measure exists (G. N. Rao et al., 1996) but this time effect is about two years. In the current evaluation plan, the time between pre-test and post-test is only one month time. Therefore, the time effect can be considered as negligible. The mean incontinence episodes before and after treatment would be analyzed by paired t-test. It is believed that the proposed change would at least reduce one episode of incontinence per week, which is the primary outcome to be measured. Anomanometry is decided not to be included in the evaluation plan because the manometric results did not predict the success or failure of biofeedback in fecal incontinence (Bartlett et al., 2011; Y. H. Ho et al., 1996; Ko et al., 1997). The secondary outcome to be measured is the Fecal Incontinence Severity Index (Rockwood et al., 1999) (Appendix 6) and it will be analyzed by paired t-test. The Fecal Incontinence Quality of Life Scale (Rockwood et al., 2000) (Appendix 5) would be used as the measurement tool and Wilcoxon rank-sum test would be used for the analysis. The patients’ acceptability and satisfaction will also be assessed by questionnaire in a five point Likert scale and analyzed by Wilcoxon signed-rank test.
Healthcare providers’ outcomes focus on the level of satisfaction among referrers, operators and the liaising staff. The outcomes would be collected by questionnaire (Appendix 10) and interview. The interview is semi-structured and would be used to elicit opinions of the procedure, the impact on the current practice and workload, the effort needed to follow the protocol and the difficulties of the implementation. The skills involved and the workflow would be assessed by a specially designed checklist.

For evaluating the system outcome, the utilization rate (i.e. the number of cases has been implemented per month), the accessibility of the innovation (i.e. the number of cases has been referred per month), the number of enterostomal therapist deployed per month, and how much has spent on the consumables from the procurement department would be evaluated. Any complaints or compliments received by the Public Relationship Office or the clinic would also be taken into consideration.

**Conclusion**

After gathering current evidences of biofeedback on improving intractable fecal incontinence after rectal surgery and conducting a quality assessment of the selected studies, an evidence-based protocol on how to implement the biofeedback treatment in the current practice was established. As described in Lewin (1947) change model, unfreeze the status quo, change the practice and freeze into a new equilibrium are the three essential steps for changing the current practice. By introducing information such as the need for changes, the current evidences, the newly developed protocol and the comprehensive planning with expected difficulties, and the possible solutions, stakeholders will be prepared, convinced and motivated to take in the proposed change. The change would then be monitored and evaluated. Necessary modifications would be carried out for sustaining the change. The ultimate goal of this proposed change is to benefit more patients with this evidence-based
practice, which focuses on improving patients’ bio-psycho-social wellbeing in terms of decreased soiling, improved quality of life and better social functioning.
References


Hospital Authority. (2000). *Position statement on holistic care* Hong Kong.


http://www.ha.org.hk/visitor/ha_visitor_index.asp?Content_ID=10008&Lang=ENG&Dimension=100&Parent_ID=10004&Ver=HTML

Hospital Authority. (2010b). Introduction of clusters: Hong Kong West Cluster Retrieved 7th Jan, 2012, from


Queen Mary Hospital. (1996). Nursing Philosophy.


of surgery and patients’ characteristics. *Diseases of the Colon & Rectum, 48*(12), 2180-2191.


## Appendix 1

### Search Strategies, Databases and Results

<table>
<thead>
<tr>
<th>Search Strategy</th>
<th>Medline (Ovid)</th>
<th>Medline (EBSCOhost)</th>
<th>Cochrane Library</th>
<th>Pubmed</th>
<th>CINAHL Plus</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) “biofeedback” or “biofeedback therapy” (Limit to “full text”, and “ English” and year= “1990-2012”)</td>
<td>2176</td>
<td>773</td>
<td>7366</td>
<td>5044</td>
<td>345</td>
</tr>
<tr>
<td>2) “fecal incontinence” or “ anterior resection syndrome” or “ bowel dysfunction” or “ post rectal surgery” or “ rectal cancer” (Limit to “full text”, and “ English” and year= “1990-2012”)</td>
<td>8343</td>
<td>2035</td>
<td>2765</td>
<td>197244</td>
<td>411</td>
</tr>
<tr>
<td>3) #2 AND “outcome” or “ effects” or “ short-term outcome” or “ long term outcome” (Limit to “full text”, and “ English” and year= “1990-2012”)</td>
<td>3291</td>
<td>1010</td>
<td>1440</td>
<td>74010</td>
<td>164</td>
</tr>
<tr>
<td>4) #1 AND #2</td>
<td>182</td>
<td>38</td>
<td>103</td>
<td>387</td>
<td>4</td>
</tr>
<tr>
<td>5) #1 AND #3</td>
<td>31</td>
<td>22</td>
<td>87</td>
<td>197</td>
<td>2</td>
</tr>
<tr>
<td>6) Limit #4 to inclusion criteria and absence of exclusion criteria</td>
<td>8</td>
<td>4</td>
<td>9</td>
<td>11</td>
<td>1</td>
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<tr>
<td>Final number of studies chosen</td>
<td>5</td>
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</table>
# Appendix 2

## Table of Evidence

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study design</th>
<th>Participant characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
<th>Limitations/remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y. H. Ho et al. (1996)</td>
<td>Pre and post test</td>
<td>Male vs Female: 10:3</td>
<td>Visual feedback by monitor</td>
<td>Data before biofeedback intervention</td>
<td>5 weeks</td>
<td>Stool frequency/day, Incontinence episodes/day, Antidiarrheal usage, MRP, MSP, Initial sensation</td>
<td>Stool frequency (Pre vs Post): AR 8.7 vs 4.6 (p&lt;.05) TC 6.2 vs 3.3 (p&lt;.05), Incontinence episodes: AR 2.7 vs 0.4 (p&lt;.05) TC 2.4 vs 0.5 (p&lt;.05), Antidiarrheals: AR 6 vs 1 (p&lt;.05) TC 6 vs 2 (p&lt;.05)</td>
<td>Small number of participants, No control group</td>
</tr>
<tr>
<td></td>
<td>Level III +</td>
<td>Mean Age: 62.1</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Failed 6 months</td>
<td>Antidiarrheal 4 RT 7AR 6 TC</td>
<td>Pelvic floor exercise at home</td>
<td>10 months</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Mean months after surgery 27.9 (n=13)</td>
<td></td>
<td>Rectal balloon</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Visual feedback by monitor</td>
<td>Once weekly for four week and 1 hour session</td>
<td>10.6 months</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Intervention</td>
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<tr>
<td>Bartlett et al. (2011)</td>
<td>Pre and post test</td>
<td>Mean age: 64.1</td>
<td>Computer assisted visual feedback</td>
<td>Data before biofeedback intervention</td>
<td>8 weeks</td>
<td>CS, FIQL, Anal canal length, MRP, MSP, Initial sensation of rectal volume, Maximum tolerated volume, VAS for satisfaction</td>
<td>Pre vs Post CS: 9 vs 6 (p=0.001), Reduced soil and liquid fecal leakage (p=0.001), Stool frequency: 5.0 vs 2.9 (p=0.003), Subjective rating of bowel control: 3.3 vs 7.3 (p=0.006), FI QoL subscales: lifestyle 2.8 vs 3.5 (p = 0.001), coping 2.1 vs 2.9 (p = 0.001), embarrassment 3 vs 3.3 (p = 0.001), Satisfaction rating 8.0 (IQR 7-9.75), MRP: 29.4 vs 29.4 (p= 0.913), MSP: 66.2 vs 82.4 (p= 0.235), Volume of initial sensation 40.0 vs 25.0 (p= 0.135), Volume at first urge 80.0 vs 60.0 p=0.097, Maximum tolerable volume (ml) 105.0 vs 115.0 p=0.635</td>
<td>Small number of participants, Guidance in coping strategies such as diet modification, fluid and supplement intake, and urgency control very helpful.</td>
</tr>
<tr>
<td></td>
<td>Level III +</td>
<td>Male vs Female: 10:9</td>
<td>4 out patient session total 4 weeks (1 hours)</td>
<td>Coping strategies, dietary advice, bowel diary, home practice.</td>
<td>24 year</td>
<td>CS, FIQL, Anal canal length, MRP, MSP, Initial sensation of rectal volume, Maximum tolerated volume, VAS for satisfaction</td>
<td>CS, FIQL, Anal canal length, MRP, MSP, Initial sensation of rectal volume, Maximum tolerated volume, VAS for satisfaction</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>3 AR 10 ultra low AR 2 Right hemicolectomy 4 proctocolectomy with IPAA</td>
<td>Computer assisted visual feedback</td>
<td>4 weeks home practice with mean duration 7 weeks</td>
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<tr>
<td></td>
<td></td>
<td>Failed standard care for 6-12 month median duration after OT 18 months (n=19)</td>
<td>Computer assisted visual feedback</td>
<td>4 weeks home practice with mean duration 7 weeks</td>
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</table>

RT= Radiotherapy; AR= Anterior Resection; TC= Total Colectomy; MRP= Maximal resting pressure; MSP= Maximal squeeze pressure; NS= Not significant; CS= Continence Grading Scale; FIQL= Fecal Incontinence Quality of Life Scale
<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study design</th>
<th>Participant characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
<th>Limitations/ remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kim et al. (2011)</td>
<td>Pre and post test</td>
<td>Level III +</td>
<td>Age: 58.1+/−10.1 Male: Female 49:21 Time to biofeedback post op (month) Mean 25.5, Anastomotic height 4.1 cm (1−9) 30 Preop RT 19 Postop RT 58 FI (82.9%)</td>
<td>Visualize by monitor and EMG. Coordination, sensory and strength training Once weekly for 10 weeks Sphincter exercise at home.</td>
<td>Data before biofeedback intervention</td>
<td>10 weeks</td>
<td>The Cleveland Clinic FI score, Number of bowel movements per day, Need for antidiarrheals, Rectal capacity</td>
<td>Pre vs Post FI score: 13.0 vs 8.4 (p&lt;.001) Number of bowel movements: 9.4 vs 5.8 (p&lt;.001) Antidiarrheal: 24 vs 9 (p&lt;.001) MRP: 39.1 vs 44.9 (p=.010) MSP: 136.4 vs 162.7 (p=.006) Rectal capacity: 102.3 vs 120.3 (p=.003) RAIR: 5 vs 8 (p&lt;.001) Mean VAS score: 61.9+/−27.6</td>
</tr>
<tr>
<td>Heymen et al. (2009)</td>
<td>RCT</td>
<td>Level II +</td>
<td>Mean Age: 59.6 Male: Female 83:25 Biofeedback vs PFE Symptoms persisted for 1 year (n=70)</td>
<td>1. Biofeedback with manometry catheter with balloon and computerized display during sessions (n=45) 2. Pelvic floor exercise one-hour training visits 96 (once/2week) Home practice times/day (n=63)</td>
<td>Standard education and advice (n=35)</td>
<td>One hour session every two week for 6 times 3-month follow-up then 12-month follow-up</td>
<td>FSI, FIQL, Fecal incontinence Adequate relief Attitudes toward treatment Spielberger State-Trait Anxiety Inventory (STAI) Beck Depression Inventory (BDI) EMG Squeeze pressure Abdominal tension</td>
<td>FSI scores: 3-month follow up F=6.82 (p=.01, ANOVA) 12-month follow up F=4.83 (p=.03, ANOVA) Days of FI per week: 0.83+/− 1.5 vs 1.6+/− 2.0, (p=.083) Complete continence: 44% vs 21%, (χ^2 = 7.0, p&lt;.008) Use of loperamide or fiber use: NS Adequate relief: 3-month follow up 76% vs. 41% (χ^2=12.5, p&lt;.001) 12-month follow up: 53% vs 35% (χ^2=3.64, p=.056) FIQL: improved in both group r=3.8 (p&lt;.0001), NS between group (p=.64) BDI, STAI: NS PFM Squeeze pressure (mmHg): 86.2 vs 64.76 (p=.014) EMG (µV): 9.6 vs 19.4 (p=.001, ANOVA) Threshold (ml): 16.1 vs 17.8 (p=.52)</td>
</tr>
</tbody>
</table>

RT= Radiotherapy; FI= fecal incontinence; RAIR= Rectoanal inhibitory reflex; VAS= Verbal analogue scale; FISI= Fecal Incontinence Severity Instrument; PFM= pelvic floor muscle; PFE= pelvic floor exercise; STAI= State-Trait Anxiety Inventory; BDI= Beck Depression Inventory; EMG= electromyogram; MRP= Maximal resting pressure; MSP= Maximal squeeze pressure; NS= Not significant; FIQL= Fecal Incontinence Quality of Life Scale
<table>
<thead>
<tr>
<th>Study design</th>
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<th>Effect size</th>
<th>Limitations/remarks</th>
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</thead>
<tbody>
<tr>
<td>Non-randomized control trial</td>
<td>Level II</td>
<td>Pelvic floor muscle strength, sensory and coordination training by balloon</td>
<td>Fiber supplements, antidiarrheal medication</td>
<td>45 mins per session</td>
<td>Self-reported episodes of incontinence per year</td>
<td>Treated vs untreated: Reduction in the number of episodes &gt; 75%: 86% vs 26% (p&lt;0.001)</td>
<td>Biofeedback is effective for patients with fecal incontinence to form stool. Opt for treatment has the keener need for treatment. Self selected due to social variable and other factors. Clinical improvement is maintained on long-term follow-up.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5 sessions (ever two week x 3 then once month x 2)</td>
<td>(n=40)</td>
<td>Total 14 weeks</td>
<td>Stool consistency and frequency of Antidiarrheal medication</td>
<td>Percentage using pad by the end: 36.5% vs 47.6%</td>
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<tr>
<td></td>
<td></td>
<td>45 minutes for each session</td>
<td>Anorectal surgery (n): 27 vs 6 (p=0.03)</td>
<td></td>
<td>The use of perineal pad</td>
<td>Start using pad after treatment: 63% vs 33.3%</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Home anal sphincter exercise (n=79)</td>
<td>Anal manometry</td>
<td></td>
<td>Satisfaction by participants Collaboration by rate by nurse</td>
<td>55.2% better, 28.2% unchanged, 16.6% worse after treatment</td>
<td></td>
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<tr>
<td></td>
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<td></td>
<td>On outcome: Better 91% vs 35% Unchanged 1.3% vs 17.5% (p&lt;0.001)</td>
<td></td>
</tr>
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<td></td>
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<td></td>
<td>Collaboration: Reduction in the number of episodes &lt; 75%; Good vs not good 4.3% vs 25% (p=0.03) 6mths: 47.9% 5yrs: 61.3%</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix 3

**Critical Appraisal Skills Programme on Selected Studies**

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1. Did the study ask a clearly focused question?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Comments:</td>
<td>The aim of the study was clearly stated, although the study question was not mentioned.</td>
<td>The aim of the study was clearly stated, although the study question was not mentioned</td>
<td>The aim of the study was clearly stated, although the study question was not mentioned</td>
<td>The study question was mentioned.</td>
</tr>
<tr>
<td>2. Was this a randomized controlled trial and wait it appropriately so?</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Comments:</td>
<td>Pre-test</td>
<td>Pre-test</td>
<td>Pre-test</td>
<td>Intervention, randomization and control were present</td>
</tr>
<tr>
<td>3. Were participants appropriately allocated to intervention and control group?</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
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<td>---</td>
</tr>
<tr>
<td>The study design is pre-post test. No control group in the study</td>
<td>The study design is pre-post test. No control group in the study</td>
<td>The study design is pre-post test. No control group in the study</td>
<td>Controlled clinical trial with no randomization</td>
<td>Participants were randomized into invention and control groups by randomization table produced by co-investigator</td>
<td></td>
</tr>
</tbody>
</table>

4. Were participants, staff and study personal ‘blind’ to participants’ study group?  
   Comments: Blinding to participants’ study group was not possible, as they need to be involved in intervention provided. However, possible outcome was assessed by independent study personal.
   
5. Were all of the participants who entered the trial accounted for at its conclusion?  
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannot tell</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Cannot tell</td>
</tr>
<tr>
<td>----------------</td>
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<td>-------------------</td>
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<td>---------------------</td>
</tr>
<tr>
<td>6. Were all of the participants in all groups followed up and data collected in the same way?</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Comments</td>
<td>All participants were follow up in the same way. The instrument for data collection was the same.</td>
<td>All participants were follow up in the same way. The instrument for data collection was the same.</td>
<td>Not all participants were follow up with regular anal mammography assessment. The instrument for data collection was the same.</td>
<td>All participants were follow up in the same way. The instrument for data collection was the same.</td>
<td>All participants were follow up in the same way. The instrument for data collection was the same.</td>
</tr>
<tr>
<td>7. Did the study have enough participants to minimize the play of chance?</td>
<td>No</td>
<td>No</td>
<td>Cannot tell</td>
<td>Cannot tell</td>
<td>Yes</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------</td>
<td>------------------------</td>
<td>------------------</td>
<td>----------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Sample size</td>
<td>The sample size was small. (n=13)</td>
<td>The sample size was small (n=19)</td>
<td>Estimated number of participants was not known, as power calculation was not reported.</td>
<td>Estimated number of participants was not known, as power calculation was not reported.</td>
<td>Power calculation was reported and hence estimated number of subjects was mentioned.</td>
</tr>
<tr>
<td>8. How are the results presented and what is the main result?</td>
<td>The results were presented to report the change of episode and parameters between pre and post test. Stool frequency: AR: 8.7 vs 4.6 (p&lt;0.05) TC: 6.2 vs 3.3 (p&lt;0.05) Incontinence episodes: AR: 2.7 vs 0.4 (p&lt;0.05) TC: 2.4 vs 0.5 (p&lt;0.05)</td>
<td>The results were presented to report change of frequency and parameters between pre and post test. Stool frequency: AR: 8.7 vs 4.6 (p&lt;0.05) TC: 6.2 vs 3.3 (p&lt;0.05)</td>
<td>The results were presented to report the change of frequency and parameters between pre and post test. Stool frequency: AR: 8.7 vs 4.6 (p&lt;0.05) TC: 6.2 vs 3.3 (p&lt;0.05) Incontinence episodes: AR: 2.7 vs 0.4 (p&lt;0.05) TC: 2.4 vs 0.5 (p&lt;0.05)</td>
<td>The results were presented as proportion. Reduction in the number of fecal incontinence episodes &gt;75% (treated vs untreated): 86% vs 26% (p&lt;0.001) Better 91% vs 35% Unchanged 1.3% vs 7.5% (p&lt;0.001) Number of bowel movements: 9.4 vs 5.8 (p&lt;0.001) Mean VAS score: 1.9+/−27.6</td>
<td>The results were presented as proportion and mean differences together with SD. Day of FI per week: 0.83+/−1.5 vs 1.6+/−2.0 (p = 0.083) Complete continence: 44% vs 21%</td>
</tr>
<tr>
<td>9. How precise are these results?</td>
<td>p&lt;.05</td>
<td>p&lt;.001</td>
<td>p&lt;.001</td>
<td>95% CI p&lt;0.001</td>
<td>P&lt;0.01</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------</td>
<td>------------------</td>
<td>---------------------</td>
<td>---------------------</td>
<td></td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Confidence interval was not reported, but p value was stated.</td>
<td>Confidence interval and p-value were reported.</td>
<td>Mean with SD and p-value were reported.</td>
<td>Mean with SD and p-value were reported.</td>
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<tr>
<td>10. Were all important outcomes considered so the results can be applied?</td>
<td>Cannot tell</td>
<td>Cannot tell</td>
<td>No</td>
<td>Cannot tell</td>
<td>Cannot tell</td>
</tr>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>As the sample size was small, it was not appropriate to give generalization of the results.</td>
<td>As the sample size was small, it was not appropriate to give generalization of the results.</td>
<td>A preliminary study was done as basis for further prospective studies.</td>
<td>Generalization of results to other study group and other settings was not mentioned.</td>
<td></td>
</tr>
</tbody>
</table>

| Conclusion:          | Level III +            | Level III +      | Level III +         | Level II +          | Level II ++          |
# Appendix 4

The implementation timeline

<table>
<thead>
<tr>
<th>Week</th>
<th>1</th>
<th>3</th>
<th>5</th>
<th>7</th>
<th>9</th>
<th>11</th>
<th>13</th>
<th>15</th>
<th>17</th>
<th>21</th>
<th>35</th>
<th>40</th>
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</thead>
<tbody>
<tr>
<td>Identify and talk to the stakeholders</td>
<td>1&lt;sup&gt;st&lt;/sup&gt;-3&lt;sup&gt;rd&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identification of problem</td>
<td></td>
<td>2&lt;sup&gt;nd&lt;/sup&gt;-4&lt;sup&gt;th&lt;/sup&gt;</td>
<td></td>
<td></td>
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<tr>
<td>Revising the proposals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4&lt;sup&gt;th&lt;/sup&gt;-6&lt;sup&gt;th&lt;/sup&gt;</td>
<td></td>
<td></td>
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<tr>
<td>Pilot study</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6&lt;sup&gt;th&lt;/sup&gt;-10&lt;sup&gt;th&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data analysis and refining of the guideline implementation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10&lt;sup&gt;th&lt;/sup&gt;-14&lt;sup&gt;th&lt;/sup&gt;</td>
<td></td>
<td></td>
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<tr>
<td>Actual study</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>10&lt;sup&gt;th&lt;/sup&gt;-14&lt;sup&gt;th&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data analysis of actual study</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>35&lt;sup&gt;th&lt;/sup&gt;-40&lt;sup&gt;th&lt;/sup&gt;</td>
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<td>Report findings</td>
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<td></td>
<td></td>
<td>40&lt;sup&gt;th&lt;/sup&gt;</td>
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<tr>
<td>Evaluation</td>
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<td></td>
<td></td>
<td></td>
<td>10&lt;sup&gt;th&lt;/sup&gt;-40&lt;sup&gt;th&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 5

Fecal incontinence Quality of Life Scale


<table>
<thead>
<tr>
<th>Q2. Due to accidental bowel leakage:</th>
<th>Most of the Time</th>
<th>Some of the Time</th>
<th>A Little of the Time</th>
<th>None of the Time</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. I am afraid to go out</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>b. I avoid visiting friends</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>c. I avoid staying overnight away from home</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>d. It is difficult for me to get out and do things</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>like going to a movie or to church</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. I cut down on how much I eat before I go out</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>f. Whenever I am away from home, I try to stay near a</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>restroom as much as possible</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>g. It is important to plan my schedule (daily activities)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>around my bowel pattern</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. I avoid traveling</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>i. I worry about not being able to get to the toilet in</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>time</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>j. I feel I have no control over my bowels</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>k. I can’t hold my bowel movement long enough to get to</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>the bathroom</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>l. I leak stool without even knowing it</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>m. I try to prevent bowel accidents by staying very near a</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>
Q 3: Due to accidental bowel leakage, indicate the extent to which you AGREE or DISAGREE with each of the following items. (If it is a concern for you for reasons other than accidental bowel leakage then check the box under Not Apply, N/A).

<table>
<thead>
<tr>
<th>Q3. Due to accidental bowel leakage:</th>
<th>Strongly Agree</th>
<th>Somewhat Agree</th>
<th>Somewhat Disagree</th>
<th>Strongly Disagree</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. I feel ashamed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>b. I can not do many of things I want to do</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>c. I worry about bowel accidents</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>d. I feel depressed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>e. I worry about others smelling stool on me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>f. I feel like I am not a healthy person</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>g. I enjoy life less</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>h. I have sex less often than I would like to</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>i. I feel different from other people</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>j. The possibility of bowel accidents is always on my mind</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>k. I am afraid to have sex</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>l. I avoid traveling by plane or train</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>m. I avoid going out to eat</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
<tr>
<td>n. Whenever I go someplace new, I specifically locate where the bathrooms are</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>☐</td>
</tr>
</tbody>
</table>

Q 4: During the past month, have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile?

1 ☐ Extremely So - To the point that I have just about given up
2 ☐ Very Much So
3 ☐ Quite a Bit
4 ☐ Some - Enough to bother me
5 ☐ A Little Bit
6 ☐ Not At All

Scale Scoring

Scales range from 1 to 5, with a 1 indicating a lower functional status of quality of life. Scale scores are the average (mean) response to all items in the scale (e.g., add the responses to all questions in a scale together and then divide by the number of items in the scale. Not Apply is coded as a missing value in the analysis for all questions.)

Scale 1. Lifestyle, ten items: Q2a Q2b Q2c Q2d Q2e Q2g Q2h Q3b Q3i Q3m

Scale 2. Coping/Behavior, nine items: Q2f Q2i Q2j Q2k Q2m Q3d Q3h Q3j Q3n

Scale 3. Depression/Self Perception, seven items: Q1 Q3d Q3f Q3g Q3i Q3k Q4, (Question 1 is reverse coded)

Scale 4. Embarrassment, three items: Q2l Q3a Q3e
Appendix 6

Fecal Incontinence Severity Index


A

<table>
<thead>
<tr>
<th></th>
<th>2 or More Times a Day</th>
<th>Once a Day</th>
<th>2 or More Times a Week</th>
<th>Once a Week</th>
<th>1 to 3 Times A Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mucus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liquid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Solid</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

B

<table>
<thead>
<tr>
<th></th>
<th>2 or More Times a Day</th>
<th>Once a Day</th>
<th>2 or More Times a Week</th>
<th>Once a Week</th>
<th>1 to 3 Times A Month</th>
<th>Never</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Gas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Mucus</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Liquid Stool</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>d. Solid Stool</td>
<td></td>
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</tbody>
</table>

Figure 1. Fecal Incontinence Severity Index. A. Event × frequency matrix presented to surgeons and patients to develop weightings and overall severity scores. Participants were instructed to rank the importance of each cell by placing a “1” in the most severe cell and a “20” in the least severe cell. B. Fecal Incontinence Severity Index Question. Presented to the fecal incontinence study population, the question asked, “For each of the following, please indicate on average how often in the past month you experienced any amount of accidental bowel leakage. (Check only one box per row).”
Appendix 7

Bowel Diary


Appendix 8
Scottish Intercollegiate Guidelines Network
Key to evidence statements and grades of recommendations

Levels of evidence

1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1- Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++ High quality systematic reviews of case control or cohort or studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3 Non-analytic studies, e.g. case reports, case series

4 Expert opinion

Grades of recommendations

A At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+

C A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++

D Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+
Appendix 9

Audit form

Name (optional)

**Screening**

<table>
<thead>
<tr>
<th></th>
<th>Achieved</th>
<th>Partially achieved</th>
<th>Not achieved</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Have screened the medical records of the clients for target selection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Have identified every single eligible client correctly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Have explained the purpose of the project and its flow</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>4.</td>
<td>Have explained in details to those eligible clients and obtain informed consent before implementation of intervention.</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>5.</td>
<td>Have conducted a questionnaire with physical examination before the start</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**FIRST SESSION OF THE PROGRAM**

<table>
<thead>
<tr>
<th></th>
<th>Achieved</th>
<th>Partially achieved</th>
<th>Not achieved</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Have provided the 45 minute to 1 hour training session on the first session</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Have used the instrument-assisted biofeedback properly</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Have explained the steps in using biofeedback clearly with instructions</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4.</td>
<td>Have provided a stool diary to monitor client’s progress</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>5.</td>
<td>Have instructed the clients to do pelvic exercise at home as prerequisites</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Follow-up sessions

<table>
<thead>
<tr>
<th></th>
<th>Achieved</th>
<th>Partially achieved</th>
<th>Not achieved</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Have provided the education on dietary modification and standard care incorporated with the biofeedback therapy</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>2. Have provided periodic reinforcements to clients on subsequent sessions</td>
<td></td>
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<tr>
<td>3. Subsequent follow-ups at the 3-months intervals to evaluate the outcome</td>
<td></td>
<td></td>
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<tr>
<td>4. Psychological needs and concerns have been addressed</td>
<td></td>
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<tr>
<td>5. Have assessed client’s satisfaction on the use of biofeedback</td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 10

Evaluation form

Name (Optional):

Please circle the appropriate box on your preferences.


## Project content

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Increase my self-care knowledge</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Improve my self-care skills</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Project is easy to follow with clear instructions</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Project duration is enough</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

## Facilitator effectiveness

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Knowledge on the new project with evidence-based support</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. Well organized program</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>3. Active in answering questions/enquires on follow-ups</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>4. Detailed explanation on the project and its usefulness</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Do you think this biofeedback project is useful for you in daily practice?  **YES / NO**

Comments:

Do you think this biofeedback project should be recommended to others in need?  **YES / NO**

Comments:

__________________________________________________________

__________________________________________________________

__________________________________________________________

Overall comments: