PROTOCOL

A randomized controlled trial examining the effectiveness of a STOMA psychosocial intervention programme on the outcomes of colorectal patients with a stoma: study protocol

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Abstract

Aims. To report a study protocol that evaluates the effects of a psychosocial intervention on patients with a newly formed stoma.

Background. With the loss of a significant body function and distorted body image, stoma patients experience physical, psychological and social challenges. Nurses have an important role in helping patients' make a smooth transition to living with their stoma. Limited studies have examined the effects of psychosocial interventions on improving stoma-related health outcomes.

Design. A randomized controlled trial is planned.

Methods. Eighty-four patients with newly formed stoma in a tertiary hospital in Singapore (Research Ethics Committee approval obtained in January 2013) will be recruited. Participants will be randomly assigned to either a control group who receive routine care or an intervention group who receive STOMA psychosocial intervention besides routine care. Outcome variables include stoma care self-efficacy, days to stoma proficiency, length of hospital stay, acceptance of stoma, anxiety and depression and quality of life. Data will be collected at four time points: before randomization and intervention (baseline), on the day of discharge (mid-intervention), at 4 weeks after discharge (postintervention 1) and at 4 months after discharge (postintervention 2).

Discussion. This study will develop a psychosocial intervention programme, which may improve patients' stoma-related outcomes. The findings will provide direction to health professionals about education and the type of support that could be offered to patients concerning stoma care in the hospital setting, which will eventually improve their quality of life.

Keywords: anxiety, colorectal cancer, depression, experiences, psychosocial intervention, quality of life, self-efficacy, stoma

> **Why is this research needed?**
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> - Patients with stoma experience physical, psychological and social challenges. It is imperative to develop more systematic, culturally appropriate care that considers patients' physical, psychological and social well-being. Offering this care to patients with a newly formed stoma will improve their self-efficacy in stoma care, acceptance of their stoma and eventually their psychological well-being and quality of life.
> - Previous studies specifically focus on colorectal patients with a stoma and mainly relate to preoperative teaching in stoma care, which improves stoma care efficiency. No studies have examined the use of psychosocial intervention specifically for colorectal patients.

Introduction

Colorectal cancer is the most predominant cancer in males and second in females between 2005–2009 in Singapore (Singapore Cancer Registry 2010). According to Kamangar *et al.* (2006), about 1,023,256 patients were diagnosed with colorectal cancer and 529,020 died from this cancer annually worldwide, making it one of the top three leading causes of cancer-related deaths. Based on statistics in Singapore General Hospital in 2007, anterior resection, abdomino-perineal resection and hemicolectomy are among the top 10 surgeries undertaken in the colorectal surgical unit to treat colorectal cancer. To improve patients' condition and quality of life, it is common to have a stoma formed.

Background

With the loss of a significant body function and distorted body image, patients with stoma often experience challenges physically, psychologically and socially (Bekkers *et al.* 1996). Patients reported a change in physical functioning, accompanied by complications of leakage, skin and stoma problems and/or odour (Nugent *et al.* 1999, Burch 2005, 2011, Black 2011). The psychological challenges include anxiety, depression and body image disturbance (Martinez 2005, Ross *et al.* 2007), which may lead to reduced self-esteem, unhealthy self-concept and sexual disorder (Grogan 2008). Previous studies also reported that patients had avoidance behaviour, poor relationship with others and were fear of social interaction (Silva *et al.* 2003, Simmons *et al.* 2007).

Stoma acceptance level among patients was low (Simmons *et al.* 2007, Chao *et al.* 2010). Poor stoma acceptance may lead to physical and psychological adaptation difficulty, affect days to stoma proficiency and prolong hospital stay postoperatively (Chaudhri *et al.* 2005, Simmons *et al.* 2007). According to the World Health Organization, quality of life of a person is defined by the functioning of the physical, psychological and social components, together with both positive aspects of one's well-being and negative aspects of present disease and disability (Till *et al.* 1984). Previous studies (Kopp *et al.* 2004, Wilson *et al.* 2006) regarding the patients' quality of life with stoma revealed that the presence of a stoma led to significant impairment of patients' physical, social, cognitive and emotional functioning, as a result leading to a negative influence on their quality of life. Other studies have demonstrated the importance of stoma care self-efficacy as an essential predictor of the acceptance of stoma and quality of life among those with colorectal cancer (Cunningham & Lockwood 1991, Simmons *et al.* 2007, Wu *et al.* 2007). Patients with lower stoma care self-efficacy may have reduced stoma acceptance and poor quality of life.

It has been highlighted in previous studies of the importance of promoting stoma self-care during psychological adaptation after surgery (Martinez 2005, O'Connor 2005, Borwell 2009a,b). Stoma self-care encompasses patients learning to manage their stoma independently (O'Connor 2005). Self-efficacy and subsequent stoma management skills may be greatly improved by pre- and postoperative programmes that improve patients' knowledge and skills. Studies revealed that patients are most receptive to information provided just before surgery (Hampton & Bryant 1992).

A review of literature shows that two studies conducted interventions involving pre-admission education and counselling by stoma nurses (Chaudhri *et al.* 2005, Bryan & Dukes 2010). Chaudhri *et al.* (2005) conducted a study in Newcastle of the UK. Interventions included two pre-operative visits by nurses to patients' homes, during which audio-visual aids were used to educate patients about the use of the stoma pouching system. The patient was assessed for proficiency in changing stoma pouches at the end of the second visit. Time to stoma proficiency and length of hospital stay were reduced in the study group. Bryan and Dukes (2010) implemented an enhanced recovery programme in Copenhagen, Denmark. Patients in the study group participated in individual practical sessions in the pre-admission clinic. Pre-operative verbal and written information was provided, along with demonstrations in emptying and changing stoma pouches using an artificial abdominal torso. Subsequently, from the first postoperative day, patients were visited and educated daily during hospitalisation. Days

to stoma proficiency and mean length of stay were reduced (Bryan & Dukes 2010).

The therapeutic effects of psychosocial interventions are well established in current systematic reviews. Quality of life in patient with cancer is improved by psycho-educational and self-care interventions, as well as the provision of emotional and social support (Devine & Cook 1983, Rehse & Pukrop 2003, Raingruber 2011, Lim *et al.* 2013). There is also an evident reduction in stress, anxiety and depression levels and proven cost-effective in reducing length of hospital stay.

Gaps in existing literature

Psychosocial interventions are used to improve health outcomes in patients with various cancers (Fukui *et al.* 2008, Girgis *et al.* 2009, Kravitz *et al.* 2011). However, interventional studies specifically focusing on colorectal patients with a stoma mainly relate to preoperative stoma care teaching (Chaudhri *et al.* 2005, Bryan & Dukes 2010). There is a lack of studies examining the use of psychosocial intervention specifically for colorectal patients. The literature revealed a gap in studies conducted in Asian countries. It is essential to investigate the effects of psychosocial intervention on stoma care self-efficacy, days to stoma proficiency, length of hospital stay, anxiety and depression level, level of stoma acceptance and quality of life in patients with colorectal cancer. In summary, like other patients with long-term illness, stoma patients would experience better psychosocial adjustment and stoma acceptance with the help of tailored psychosocial intervention programmes in pre- and postoperative periods.

Theoretical framework of the study

The theoretical framework of the STOMA psychosocial intervention programme builds on Bandura's self-efficacy theory (1977) and the conceptual framework by Simmons *et al.* (2007) (Figure 1). There is a strong correlation among patients' stoma care self-efficacy, acceptance of a stoma and interpersonal relationships. Stoma care self-efficacy has been found to aid in stoma acceptance and consequently enhance interpersonal relationships.

Self-efficacy is a cognitive process where an individual evaluates his/her ability to carry out a given task (Bandura 1977). An individual's self-efficacy is greatly influenced by four factors. The first is 'mastery experience', where positive experiences provide the necessary confidence to repeat accomplishments in future (Bandura 1977). In stoma patients, this could include confidence in stoma care. 'Vicarious experience' gained through observing others can enhance confidence when it involves observing the successful accomplishment of a task. In stoma patients, the

confidence to achieve personal success rises when they observe healthcare professionals and their family members carrying out a task for them. 'Verbal persuasion', which for stoma patients could be verbal assurance from healthcare professionals and their family members, is another critical factor in encouraging accomplishment of a task. The final factor in influencing self-efficacy involves the individual's 'physiological and affective states', or physical and emotional reactions (Bandura 1977). These may demonstrate the need to address the patient's psychosocial concerns and needs.

Acceptance is a significant element of adjustment to a disabling health state (Li & Moore 1998). According to Simmons *et al.* (2007), stoma acceptance has a direct relationship with adjustment to a stoma. Patients who accept their diagnosis adapt to it better (Abraido-Lanza *et al.* 2004). It is essential to ensure appropriate emotional acceptance with the affective internalization of the possible implications of the disability into one's self-concept, including the behavioural adaptation and reintegration into one's social life.

A supportive context is essential for coping with stressful life events, such as health-related issues. Patients often discuss health-related issues with family members, friends and healthcare professionals (Han *et al.* 2005, Friedman *et al.* 2006). Psychosocial interventions for long-term illness that include the patient's closest family members have shown positive effects on depression and anxiety (Martire *et al.* 2004). Stoma patients who have difficulties engaging with family will not be able to adjust well, influencing acceptance of stoma and stoma care self-efficacy (Simmons *et al.* 2007).

Guided by the aforementioned theory and conceptual framework, a supportive and educative psychosocial intervention programme will be developed to promote colorectal cancer patients' self-efficacy, enhance their stoma acceptance and minimize negative attitudes. This programme will consist of five core elements based around the acronym 'STOMA' (Figure 1, Table 1):

- **S**upport availability
- **T**hinking positively with acceptance
- **O**vercoming social stigma
- **M**inimizing negative feelings
- **A**nalysing self-efficacy in stoma care

The study

Aims

This study aims to develop a STOMA psychosocial intervention programme and examine its effectiveness in improving outcomes (including primary outcome of self-efficacy of
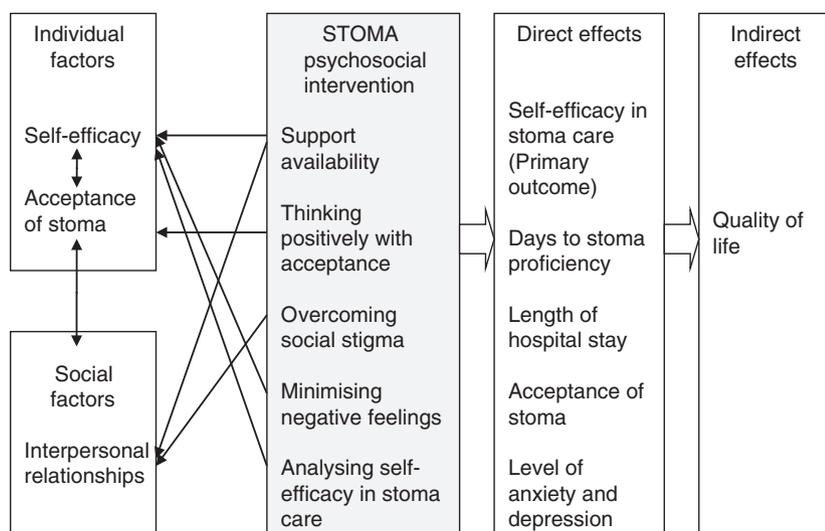
Figure 1 Theoretical framework of the study.

stoma self-care, as well as secondary outcomes of days to stoma proficiency, length of hospital stay, anxiety and depression, acceptance of stoma and quality of life) of patients with a newly formed stoma.

Objectives

- To develop a STOMA psychosocial intervention programme.
- To examine the effectiveness of the programme on the outcomes of patients with stoma, including the primary outcome of self-efficacy in stoma self-care and secondary outcomes of days to stoma proficiency, length of hospital stay, anxiety and depression, acceptance of stoma and quality of life.

Hypotheses

- Patients in the interventional group will report significantly higher levels of self-efficacy in stoma self-care than those in the control group.
- There will be a significant reduction in time to stoma proficiency, shorter length of hospital stay, lower levels of anxiety and depression, higher levels of acceptance in relation to stoma and better quality of life in patients in the interventional group than those in the control group.

Study design/Methodology

This is a quantitative, randomized controlled study with two-group pre-test and repeated post-tests that aims to examine the effectiveness of a newly developed psychosocial intervention programme on outcomes of stoma patients. At the end of the intervention, some patients will be selected for face-to-face interview to understand the strengths and weaknesses of the intervention and gather suggestions for improvement of programme. A single-blinded technique will be used in this study.

Participants

All participants will be recruited from inpatient wards and outpatient clinic of a tertiary public hospital in Singapore. The inclusion criteria include: (1) aged 21 years old and above; (2) undergoing elective colorectal resections, including both laparoscopic and open procedures, which require formation of a permanent stoma; and (3) able to read and speak English or Mandarin. The exclusion criteria include: (1) undergoing emergency operations; (2) having visual and/or hearing impairments; (3) having cognitive impairments/mental disorders identified in their medical records; and/or (4) having any surgical complication leading to a delay of more than five days before attaining stoma proficiency in the postoperative period.

Sample size determination

The sample size is calculated based on the expected difference of self-efficacy score using the Stoma Self-Efficacy Scale between the intervention and control group. We expect the difference of the self-efficacy score between the two groups post-test to be 15, with a standard deviation of 22 (110-22/4), 80% power at a 5% level of significance (2-sided), the minimum sample size is 35 per group; in total 70 (Machin *et al.* 1997, Johnson 2012). Considering 20%

Table 1 STOMA psychosocial intervention programme and element component checklist.

Theoretical framework	Five core elements	Element component	Interventions
Bandura's (1997) Self-Efficacy Theory Conceptual framework of Simmons *et al.* (2007)	Support availability (S)	(1) Encouraging open communication	1.1 Allow patients and family to openly discuss illness and concerns. 1.2 Encourage patients and family members to voice concerns and share their perspectives on the issue (pre-operative and postoperative).
		(2) Identifying family and community resources	2.1 Assist in identifying individual and family strengths in supporting patients' postoperative rehabilitation. 2.2 Provide information regarding availability of community resources and support services.
	Thinking positively with acceptance (T)	(3) Encouraging a positive attitude	3.1 Discuss positive coping skills. 3.2 Encourage positive attitude.
		(4) Promoting acceptance	4.1 Discuss common concerns of stoma patients. 4.2 Enable patients and family members to vent frustrations regarding the newly diagnosed condition. 4.3 Encourage them to verbalize perceptions of the condition and the formation of the stoma after the operation.
	Overcoming social stigma (O)	(5) Effective and healthy coping, with continuity of lifestyle behaviours	5.1 Explore and address issues and concerns in resuming activities.
		(6) Handling overwhelming stress	6.1 Discuss active and passive coping strategies. 6.2 Allow opportunities to discuss any issues or concerns with patients and family members.
	Minimize negative feelings (M)	(7) Sharing fears and negative feelings	7.1 Encourage patients and family members to share fears and negative feelings about newly diagnosed condition and operation.
		(8) Reduction in uncertainty	8.1 Provide information about the disease process and management process. 8.2 Answer questions about operation.
		(9) Adapting to uncertainty	9.1 Assist patients and family to set short-term goals so they can feel satisfied when accomplished. 9.2 Guide them to been proficient in stoma care pre-operatively to increase their confidence.
	Analyse self-care efficacy (A)	(10) Assessment of needs	10.1 Assess patient's and family's needs.
		(11) Empowering with self-care strategies	11.1 Involve patients in decision-making process regarding their stoma. 11.2 Discuss the availability of the stoma appliances with patients. 11.3 Guide patients and family members step by step to be proficient in stoma care pre-operatively. 11.4 Carry out evaluation to determine the attainment of goals.

dropout rate based on previous studies, we need a minimum of 84 patients (70 + 70 × 20%); 42 in each group. The process evaluation includes two parts: quantitative and qualitative. In the quantitative part, all participants in the intervention group will be recruited. In the qualitative part, a purposive sample ($n = 20$) from the intervention group will be invited to be involved in the postintervention interview. Participants will be selected from those who reported positive changes in stoma care self-efficacy, no changes in stoma care self-efficacy and negative changes in stoma care self-efficacy.

Randomization

The Research Randomizer (2014) will be used to generate one set of 42 unique, non-repeating numbers ranging from 1–84. Every participant ($n = 84$) will select a number from 1–84. If the selected number matches any number in the generated list, the participant will be allocated into the intervention group, or else, to the control group.

Intervention

Control group. The participants in the control group will receive routine care provided by the hospital, including routine preparation pre-operatively and education postoperatively.

Intervention group. The participants in the intervention group will receive routine care and STOMA psychosocial intervention (see details of the intervention in Table 1). The STOMA psychosocial intervention programme includes an individual psycho-education face-to-face session (pre-operatively) with booklet provided and five telephone follow-up sessions (one pre-operatively and four postoperatively) (Table 2).

The educational booklet, which is under experts' review, has been drafted based on findings from a preliminary study (Lim *et al.* 2014) and an integrative literature review (Lim *et al.* 2013) conducted by the main researcher and team (Table 2), and other literature (e.g. White 1997, Martire *et al.* 2004, Brown & Randle 2005, Antoni *et al.* 2006, Jacobsen & Jim 2006, Seaward 2006, Simmons *et al.* 2007, Williams 2008, 2012, Worster & Holmes 2008, Borwell 2009a,b, Howsepian & Merluzzi 2009, Noone 2010, Hughes *et al.* 2011, McCaughan *et al.* 2011, Raingruber 2011, Von Ah *et al.* 2013). The main contents include: (1) an introduction to psychosocial interventions; (2) an outline of the STOMA psychosocial intervention programme which focuses on encouraging open communication, identifying family resources, encouraging a positive attitude, promoting acceptance, effective and healthy coping with continuity of

lifestyle behaviours, handling overwhelming stress, sharing fears and negative feelings, reducing and adapting to uncertainty, assessment of needs and empowering with self-care strategies; (3) availability of community resources and support services; (4) common issues and concerns in resuming activities postoperatively with a stoma; (5) a step-by-step guide in stoma care training; and (6) stoma education protocol to guide participants in setting goals. Psychosocial interventions consisting of psycho-education and family support interventions will be introduced to the patient and family members at the beginning of the programme.

There will be a total of five telephone sessions (15 minutes for each session). The first session will take place pre-operatively to explore new issues and concerns after the face-to-face interactive session. The other four telephone sessions will be conducted postoperatively, focusing on exploring new issues which arise after operation and discharge.

Outcome measures

The outcome measures include patients' self-efficacy of stoma self-care (primary outcome), days to stoma proficiency, length of postoperative hospital stay, acceptance of stoma, anxiety and depression and quality of life. A Demographic and Clinical Data Sheet (DCDS) will be used to collect patients' demographic details and clinical data.

The Stoma Self-Efficacy Scale (Bekkers *et al.* 1996) will be used in this study. The Stoma Self-Efficacy Scale consists of 22 items (Cronbach's Alpha = 0·94), with five responses, ranging from 'not at all confident' to 'extremely confident'. Higher scores reflect positive self-efficacy. The Chinese version of the Stoma Self-Efficacy Scale will be used for patients who only understood and read Mandarin. The Stoma Self-Efficacy Scale was translated into Chinese and validated by Wu *et al.* (2007). The alpha coefficient for the Chinese Stoma Self-Efficacy Scale was 0·97 (Wu *et al.* 2007).

The days to stoma proficiency is defined as the number of days from date of surgery to achievement of proficiency as assessed with the protocol of standard stoma education. This protocol checklist is developed for this study, with the format and content based on the protocol used by Chaudhri *et al.* (2005). Medical record review will be used to collect data of the length of postoperative hospital stay, which is defined as the number of days from the date of surgery to the date which the patient is deemed fit for discharge by the surgical team in charge.

The Acceptance of Chronic Health Conditions Scale (ACHC scale) (Stuifbergen *et al.* 2008) is used as the measure of acceptance. This scale has a high internal consis-

Table 2 Standardized STOMA psychosocial intervention protocol.

Methods of delivery	Duration	Contents	Activities	Estimated duration (minutes)
1. Individual psycho-education session conducted pre-operatively with family involvement	Within 1–2 weeks pre-operatively	Introduce psychosocial interventions: psycho-education and family support interventions.	Give explanation	5
		1. Encourage open communication about concerns about diagnosis and treatment process and explore family and community resources.	Discussion	5
		2. Explore positive attitude and coping skills and ways to promote acceptance of diagnosis and stoma.	Discussion, teaching	5
		3. Explore effective and healthy coping, with continuity of lifestyle behaviours after formation of stoma and how to handle overwhelming stress.	Discussion	10
		4. Explore fears and negative feelings, methods of reducing uncertainty and adapting to uncertainty.	Discussion	5
		5. Assess individual needs and interact with patients to empower with self-care strategies. Use a model to demonstrate how to empty and change a single-piece stoma pouch.	Demonstration and return demonstration	30
2. Individual telephone session × 1 (pre-operatively)	Within 1 week pre-operatively	Explore new issues as they arise after the psycho-education session and answer queries.	Discussion	15
3. Individual telephone session × 4 (postoperatively)	Weekly basis (weeks 1–4) postoperatively	Explore new issues after operation and discharge and answer queries of patients.	Discussion	15 (×4)
4. Educational booklet	Provided during the psycho-education session	Use the education booklet to reinforce the face-to-face STOMA support psycho-education programme contents.		–

tency (Cronbach's alpha = 0·82). This scale measures acceptance of chronic health conditions in general. To enable participants to focus on their stoma, the phrase 'chronic health conditions' was replaced by the word 'stoma' with the advice from the author. The ACHC scale consists of 10 items, each measures on a 5-point Likert scale (1 = strongly agree, 5 = strongly disagree). Thus, higher scores indicate higher levels of acceptance. The ACHC scale has been translated into Chinese by the bilingual main researcher, which was followed by back translation done by the bilingual co-investigator and will be validated before using in this study.

Patients' level of anxiety and depression will be assessed pre-operatively, on the day of discharge and 4 weeks and

3 months postoperatively using the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith 1983). The HADS has a high internal consistency (Cronbach's Alpha = 0·83) with 14 items, which will take an average of two to five minutes to complete. It is divided into two main sections with one section focusing on anxiety, which is marked 'A', while the other focusing on depression, which is marked 'D'. Patients are advised to provide an immediate and spontaneous response. Each statement has four responses graded from 0–3. There will be a maximum possible score of 21 for both anxiety and depression. To make it a more effective and detailed tool, the scores can be further analysed: a patient scoring 11 or more on either section will be considered at risk of anxiety or depression; a patient scoring 8–10 will be considered at borderline risk of anxiety or depression. Meanwhile, patients scoring 0–7 will be in the normal range (Pritchard 2011). The Chinese version of the HADS will be used for patients who can only understand and read Mandarin. The HADS was translated into Chinese and validated (Leung *et al.* 1993).

The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Colorectal 29-item questionnaire (EORTC QLQ-CR29) will be used to measure quality of life in patients with stoma (Gujral *et al.* 2007). The QLQ-CR29 will be served to gather data on the disease-specific symptoms and adverse effects of the patients. The QLQ-CR29 is divided into four main functions assessing urinary frequency, faecal seepage, stool consistency and body image and single items assessing other common problems following treatment for colorectal cancer. There are 18 items which address gastrointestinal symptoms, pain and problems with micturition. There are separate scales and issues with micturition. There are separate scales for participants without a stoma, which are not relevant to this study and hence not mentioned. There are also separate items which address sexual function for men and women. The responses to the QLQ-CR29 were linearly converted into 0–100 scores using standard EORTC guidelines (Burch 2013). A higher score indicates worse symptoms. The Chinese version of QLQ-CR29, which was translated and validated by Peng *et al.* (2011), will be used for patients who only understand and read Mandarin. The scales demonstrated good internal consistency, with an alpha coefficient exceeding 0·7 (Notter & Chalmers 2012). This is a useful questionnaire in evaluating curatively treated patients with rectal cancer.

Process evaluation

Process evaluation will be used to identify strengths and limitations of the STOMA programme. The first section consists of a questionnaire survey which will be administered to all participants in the intervention group. The main focus will be on participants' perceived effectiveness of the psychosocial interventions and satisfaction level on completion of intervention. The second section consists of two open-ended questions which will be administered to participants who reported positive changes, no changes and negative changes in stoma care self-efficacy. Purposive selection of patients ($n = 20$) according to their stoma care self-efficacy level will be used. They will be asked to comment on the contents and delivery method of the intervention, and the effect of the presence of a family member. A face-to-face interview will be conducted with the help of an interview guide (English or Chinese).

Study procedure

The main researcher (LSH) will liaise with the clinicians and nurse managers of the relevant wards and outpatient clinic. Information on the medical records of patients who are scheduled for surgery during each month will be requested. The main researcher (LSH) will be responsible for recruitment, randomization and intervention. A research assistant will be solely in charge of conducting data collection. Before the formal data collection, a pilot study with 10 patients will be conducted to examine the study process and improve content validity of the questionnaires.

As shown in Figure 2 Consolidated Standards of Reporting Trial (CONSORT) flow chart, the data will be collected at four time points: baseline, mid-intervention (on the day of discharge, after the individual face-to-face session and first pre-operative telephone session), postintervention 1 and postintervention 2. On first contact with patients, after obtaining their written consent, demographic data will be collected and they will be requested to answer the DCDS and HADS and one question inquiring about their perceived confidence in managing their stoma before randomization. The main researcher will conduct the pre-operative intervention, consisting of the individual face-to-face psychosocial intervention session and one telephone session, at a time convenient to the patients. On the day of discharge, participants (from both intervention and control groups) will be asked to respond to HADS, ACHC Scale, Stoma Care Self-Efficacy Scale and EORTC OLQ-CR29 questionnaires; and their days to stoma proficiency and length of hospital stay will be recorded (Figure 2). Four weeks after discharge, when all four telephone sessions are completed, patients will be asked to respond to all aforementioned questionnaires again and some patients from the intervention group will be invited for the process evaluation interview. Participants will be requested to evaluate the contents
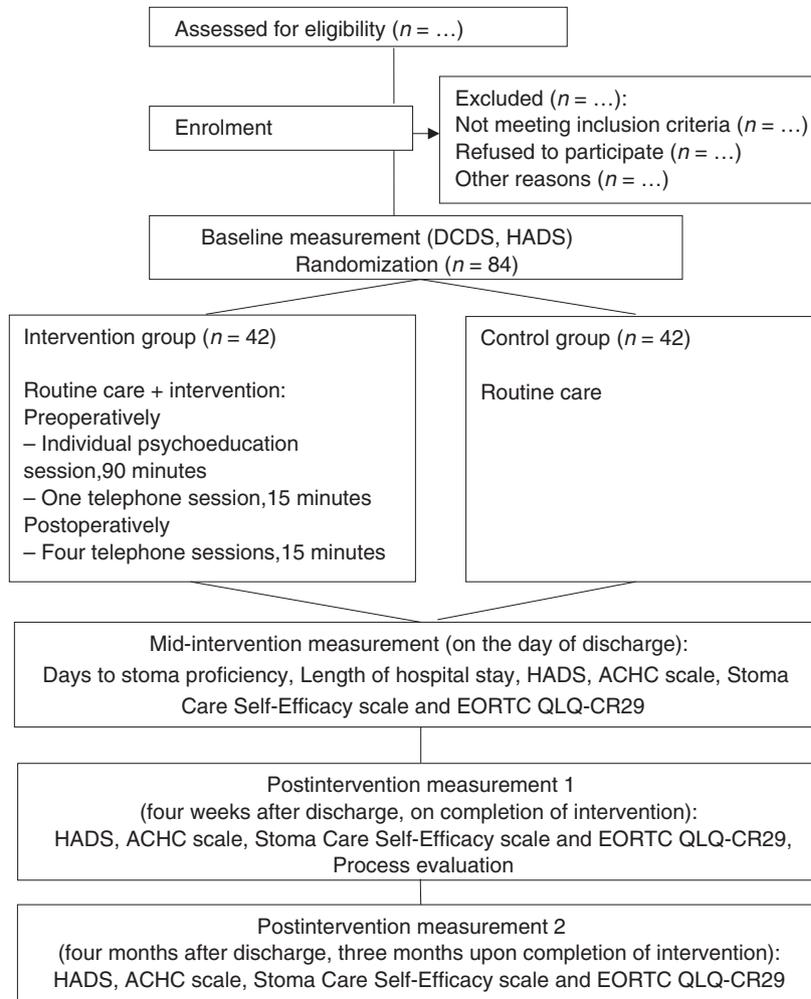
Figure 2 Consolidated Standards of Reporting Trial (CONSORT) flow chart. DCDS, demographic and clinical data sheet; ACHC, acceptance of chronic health conditions scale; HADS, hospital anxiety and depression scale; EORTC QLQ-CR29, European organization for research and treatment of cancer quality of life questionnaire colorectal 29-item questionnaire.

of the intervention, and the activities and methods of delivery. Each interview will take 20–30 minutes and will be audio-recorded. Four months after discharge, the last questionnaire survey will be conducted using the same questionnaires.

Data analysis

The IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY) will be used to analyse the quantitative data. Normality tests will be used to examine whether the scores of outcome variables are normally distributed. Cronbach's alpha value will be used to test the internal consistency of the instruments used in this study. Descriptive statistics will be used to describe the socio-demographics and clinical data, and all outcome variables. Non-parametric tests (Chi-square/Fisher's exact tests) or

parametric tests (independent t-tests/analysis of variance) will be used to examine the heterogeneity of demographic and baseline data between groups. Presuming that the outcomes are normally distributed, parametric tests will be used. Pearson Product-Moment Correlation Coefficient will be used to examine the correlation among outcome variables. Repeated measures analysis of covariance adjusted by possible confounding factors (e.g. age, gender, education level) will be used to examine the differences between groups on each outcome across four time points. Multivariate analysis of covariance adjusted by confounding factors will be used to analyse the difference of each outcome at the three time points (immediately after the face-to-face session, post-test 1 and post-test 2). The Levene's test or Barlett test will be used to examine the homogeneity of variance across the three groups (Munro 2005); P values

less than 0·05 are considered statistical significant. Intention-to-treat analysis will be used with missing values replaced by means of the variables (Gutman 2010, Shah 2011). This approach of mean substitution aims to increase the sample size and enables the variable means to remain unchanged (Munro 2005). Relative non-parametric tests will be used if the normality and homogeneity assumptions are not satisfied.

Thematic analysis will be used to analyse the qualitative data from the interviews (Holloway & Wheeler 2002, Lindseth & Norberg 2004, Braun & Clarke 2006, Houghton *et al.* 2013). Initial coding, generation of subthemes and themes will be performed. Rigour, which is evaluated by credibility, transferability, dependability and confirmability according to Lincoln and Guba (1985) (as cited in Houghton *et al.* 2013), will be taken into consideration during the study process.

Ethical considerations

Research Ethics Committee approval has been obtained from the participating hospital. A participant information sheet will be given to patients, describing the purpose and brief introduction of study. Written consent and audio-recording consent will be sought from participants after clear information about the study has been conveyed. Voluntary participation and confidentiality of identity and data will be guaranteed. The written consent will also include advice of participants to not disclose any information about the study to other patients. Should a participant be identified as having severe depression, referral will be made.

Validity and reliability

The entire set of data will be verified after collection and any issues found will be immediately amended by the researcher. Cross-checking will be done to verify data after entering in SPSS. Identification of any evident errors and outliers in the data will be carried out by descriptive analysis. When there is a need, data will be cross-checked against original sources of data. Before conducting data analysis, there will be a test of all associated statistical assumptions. This study consists of a randomized controlled trial involving repeated measures. Both groups will be compared at the beginning of their variables including clinical and demographic data, and baseline outcomes, so as to ensure equivalence. If any differences in the outcome variables are found between the two groups at baseline, there will be statistic control in the analysis.

Discussion

The feasibility of the project

The study has been approved by the Institutional Review Board of the participating hospital. A preliminary study (Lim *et al.* 2014) and literature review (Lim *et al.* 2013) have been completed. The STOMA psychosocial intervention programme has been developed based on various theories (Bandura 1997, Simmons *et al.* 2007) and the needs of patients (Lim *et al.* 2014). Instruments for data collection are available and ready to use. The estimated sample size is 84. Recruitment and intervention is expected to be completed in 1 year. A few strategies are developed to improve recruitment: (1) carrying out face-to-face on-site recruitment and phone calls; (2) providing a token of appreciation, including a token of S$100 after completing the entire intervention programme and S$15 on completion of interviews.

Current practice, preliminary findings and significance of the study

In the hospitals in Singapore, the routine stoma care is provided at two time points: pre-operatively at admission and 5 days after the operation. The routine stoma care lacks regular pre-operative education and counselling and postoperative follow-up with patients. Patients' experiences of stoma self-care and support needs have not been explored and these are very important in helping healthcare professionals to understand the areas that need to be improved in current practice.

A preliminary descriptive qualitative study explored experiences of patients in the management of their stoma, including their needs and factors that influence their self-management (Lim *et al.* 2014). Semi-structured interviews were conducted to collect data from 12 patients 1 month postoperatively in a colorectal ward in a public hospital in Singapore. This study highlights the importance of health professionals' roles in helping patients adjust pre- and postoperatively and accept the presence of a stoma. It provides evidence for health professionals to be aware of the physical, psychological and social impact of a stoma on a patient in the initial postoperative period.

A literature review (Lim *et al.* 2013) has been conducted to explore the effects of psychosocial interventions on the outcomes of colorectal cancer patients, encompassing the physical, psychological and social functions, and the influence on their quality of life. The review summarized that several psychosocial interventions, including cognitive-behavioural therapy educational interventions, supportive

group therapy and relaxation training were found to reduce patients' days to stoma proficiency, length of hospital stay and hospital anxiety and depression and leading to an improvement of their quality of life. Effective interventions include telephone sessions, home visits, individual and group teaching sessions and group sessions.

Based on current practice, the evidence from the preliminary study (Lim *et al*. 2014) and the integrative review of the literature (Lim *et al*. 2013) regarding care of a patient with a stoma, it is imperative to develop more systematic, culturally appropriate care that considers physical, psychological and social well-being of each patient with newly formed stoma. This would improve their self-efficacy in stoma care, acceptance of stoma and eventually improve their psychological well-being and quality of life. The results from the qualitative study (Lim *et al*. 2014) have been used to guide the development of the STOMA psychosocial intervention programme.

The proposed STOMA psycho-educational intervention is a relatively new initiative in Asian countries and also new to Singapore. Psychosocial adjustment and acceptance in those with a stoma could be much improved with a tailored psychosocial intervention programme across pre- and post-operative periods. Two researchers will be involved in this study, the main researcher will conduct the intervention and the other collects the data. The main researcher will strictly follow standardized STOMA psychosocial intervention protocols to ensure consistency.

If the STOMA psychosocial intervention programme is proven to be effective in this study, the psycho-educational intervention can be made available to the clinical settings and used by nurses with minimal training, as a routine programme for patients in Singapore. In the long term, if the STOMA psychosocial intervention programme is proven to be cost effective in future studies, the programme can be translated into other languages and provided to the similar group of patients in other countries. The improvement in pre-operative preparation of patients who will undergo surgery with stoma formation will improve their knowledge and psychosocial preparation. This will lead to a more positive attitude towards their stoma and better health outcomes, which will eventually lead to better quality of life.

Limitations

Participants will not be blinded to the interventions in this study as they will be well aware of the STOMA psycho-education intervention that they were receiving. The outcome variables will entirely depends on participants'

individual self-report, which may be influenced by social desirability, especially relating to level of anxiety and acceptance of the stoma.

Conclusion

A clinically effective and beneficial psycho-educational intervention programme will be identified in this study to improve patients' stoma-related outcomes by promoting more effective and independent stoma self-care, leading to better acceptance of stoma, better psychological well-being and quality of life. It is essential to conduct a randomized controlled trial to establish the benefits of the psycho-educational intervention programme before including it as part of the patient care in the hospital settings.

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No conflict of interest has been declared by the authors.

Author contributions

All authors have agreed on the final version and meet at least one of the following criteria [recommended by the ICMJE (http://www.icmje.org/ethical_1author.html)]:

- substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- drafting the article or revising it critically for important intellectual content.

References

Abraido-Lanza A., Vasquez E. & Echverria S. (2004) Religious and other forms of coping among Latinos with arthritis. *Journal of Counselling and Clinical Psychology* **72**, 91–102.

Antoni M.H., Wimberly S.R. & Lechner S.C. (2006) Reduction of cancer-specific thought intrusions and anxiety symptoms with a stress management intervention among women undergoing treatment for breast cancer. *American Journal of Psychiatry* 163, 1791–1797.

Bandura A. (1977) Self-efficacy: toward a unifying theory of behaviour change. *Psychological Review* 84, 191–215.

Bandura A. (1997) *Self-efficacy: The Exercise of Control*. Freeman, New York.

Bekkers M., van Knippenberg E., van den Borne H. & van Berge-Henegouwen G. (1996) Prospective evaluation of psychosocial adaptation to stoma surgery: the role of self-efficacy. *Psychosomatic Medicine* 58, 183–191.

Black P. (2011) Coping with common stoma problems in care homes. *Nursing & Residential Care* 13, 126–128.

Borwell B. (2009a) Continuity of care for the stoma patient: psychological considerations. *British Journal of Community Nursing* 14, 326–331.

Borwell B. (2009b) Rehabilitation and stoma care: addressing the psychological needs. *British Journal of Nursing* 18(S20–22), S24–25.

Braun V. & Clarke V. (2006) Using thematic analysis in psychology. *Qualitative Research in Psychology* 3, 77–101.

Brown H. & Randle J. (2005) Living with a stoma: a review of the literature. *Journal of Clinical Nursing* 14, 74–81.

Bryan S. & Dukes S. (2010) The Enhanced Recovery Programme for stoma patients: an audit. *British Journal of Nursing* 19, 831–834.

Burch J. (2005) The pre- and postoperative nursing care for patients with a stoma. *British Journal of Nursing* 14, 310–318.

Burch J. (2011) Stoma management: enhancing patient knowledge. *British Journal of Community Nursing* 16, 162, 164, 166.

Burch J. (2013) Care of patients with a stoma. *Nursing Standard* 27, 49–56.

Chao H., Tsai T., Livneh H., Lee H. & Hsieh P. (2010) Patients with colorectal cancer: relationship between demographic and disease characteristics and acceptance of disability. *Journal of Advanced Nursing* 66, 2278–2286.

Chaudhri S., Brown L., Hassan I. & Horgan A.F. (2005) Preoperative intensive, community-based vs. traditional stoma education: a randomised, controlled trial. *Diseases of the Colon and Rectum* 48, 504–509.

Cunningham A.J. & Lockwood G.A. (1991) A relationship between perceived self-efficacy and quality of life in cancer patients. *Patient Education and Counseling* 17, 71–78.

Devine E.C. & Cook T.D. (1983) A meta-analytic analysis of effects of psychoeducational interventions on length of postsurgical hospital stay. *Nursing Research* 32, 267–274.

Friedman L.C., Kalidas M., Elledge R., Chang J., Romero C., Husain I. & Liscum K.R. (2006) Optimism, social support and psychological functioning among women with breast cancer. *Psycho-oncology* 15, 595–603.

Fukui S., Ogawa K., Ohtsuka M. & Fuku N. (2008) A randomised study assessing the efficacy of communication skill training on patients' psychologic distress and coping nurses' communication with patients just after being diagnosed with cancer. *Cancer* 113, 1462–1470.

Girgis A., Breen S., Stacey F. & Lecathelinais C. (2009) Impact of two supportive care interventions on anxiety, depression, quality of life and unmet needs in patients with nonlocalised breast and colorectal cancers. *Journal of Oncology* 27, 6180–6190.

Grogan S. (2008) *Body Image: Understanding Body Dissatisfaction in Men, Women and Children*, 2nd edn. Routledge, New York.

Gujral S., Conroy T., Fleissner C., Sezer O., King P.M., Avery K.N.L. & Blazeby J.M. (2007) Assessing quality of life in patients with colorectal cancer: an update of the EORTC quality of life questionnaire. *European Journal of Cancer* 43, 1564–1573.

Gutman S. (2010) From the desk of the editor. Reporting standards for the intervention effectiveness studies. *American Journal of Occupational Therapy* 64, 523–527.

Hampton B. & Bryant R. (1992) *Ostomies and Continent Urinary Diversions*. Mosby, St Louis, MO.

Han W.T., Collie L., Koopman C., Azarow J., Classen C., Morrow G.R. & Spiegel D. (2005) Breast cancer and problems with medical interactions: relationships with traumatic stress, emotional self-efficacy and social support. *Psycho-Oncology* 14, 318–330.

Holloway I. & Wheeler S. (2002) *Qualitative Research in Nursing*, 2nd edn. Blackwell Science Ltd, Oxford.

Houghton C., Casey D., Shaw D. & Murphy K. (2013) Rigour in qualitative case-study research. *Nurse Researcher* 20, 12–17.

Howsepian B.A. & Merluzzi T.V. (2009) Religious beliefs, social support, self efficacy and adjustment to cancer. *Psycho-Oncology* 18, 1069–1079.

Hughes J.S., Gourley M.K., Madson L. & Blanc K.L. (2011) Stress and coping activity: reframing negative thoughts. *Teaching of Psychology* 38, 36–39.

Jacobsen P.B. & Jim H.S. (2006) Psychosocial interventions for anxiety and depression in adult cancer patients: achievements and challenges. *CA: A Cancer Journal for Clinicians* 58, 214–230.

Johnson T. (2012) Follow-up care of stoma patients: a systematic literature review. *Gastrointestinal Nursing* 10, 30–36.

Kamangar F., Dores G.M. & Andersen W.F. (2006) Patterns of cancer incidence, mortality and precalence across five continents: defining priorities to reduce cancer disparities in different geographic regions of the world. *American Journal of Clinical Oncology* 24, 2137–2150.

Kopp I., Bauhofer A. & Koller M. (2004) Understanding quality of life in patients with colorectal cancer: comparison of data from randomised controlled trial, a population based cohort study and the norm reference population. *Inflammation Research* 53, 130–135.

Kravitz R.L., Tancredi D.J. & Grennan T. (2011) Cancer health empowerment for living without pain (Ca-HELP): effects of a tailored education and coaching intervention on pain and impairment. *Pain* 152, 1572–1582.

Leung C.M., Ho S., Kan C.S., Hung C.H. & Chen C.N. (1993) Evaluation of the Chinese version of the Hospital Anxiety and Depression Scale. A cross-cultural perspective. *International Journal of Psychosomatics* 40, 29–34.

Li L. & Moore D. (1998) Acceptance of disability and its correlates. *Journal of Social Psychology* 138, 13–25.

Lim S.H., Chan W.C.S. & He H.G. (2013) Effect of psychosocial interventions on outcomes of patients with colorectal cancer: a

review of the literature. *European Journal of Oncology Nursing* **17**, 883–891.

Lim S.H., Chan W.C.S. & He H.G. (2014) Patients' experiences of performing self-care of stomas in the initial postoperative period. *Cancer Nursing*. doi:10.1097/NCC.0000000000000158.

Lincoln Y.S. & Guba E.G. (1985) *Naturalistic Inquiry*. Sage Publications, Newbury Park, CA.

Lindseth A. & Norberg A. (2004) A phenomenological hermeneutical method for researching lived experience. *Scandinavian Journal of Caring Science* **18**, 145–153.

Machin D., Campbell M., Fayers P. & Pinol A. (1997) *Sample Size Tables for Clinical Studies*, 2nd edn. Blackwell Science, Oxford.

Martinez L.A. (2005) Self-care for stoma surgery: mastering independent stoma self-care skills in an elderly woman. *Nursing Science Quarterly* **18**, 66–69.

Martire L.M., Lustig A.P., Schulz R., Miller G.E. & Helgeson V.S. (2004) Is it beneficial to involve a family member? A meta-analysis of psychosocial interventions for chronic illness. *Health Psychology* **23**, 599–611.

McCaughan E., Parahoo K. & Prue G. (2011) Comparing cancer experiences among people with colorectal cancer: a qualitative study. *Journal of Advanced Nursing* **67**, 2686–2695.

Munro B.H. (2005) *Statistical Methods for Health Care Research*, 5th edn. Lippincott Williams & Wilkins, Philadelphia, PA.

Noone P. (2010) Pre- and postoperative steps to improve body image following stoma surgery. *Gastrointestinal Nursing* **8**, 34.

Notter J. & Chalmers F. (2012) Living with a colostomy: a pilot study. *Gastrointestinal Nursing* **10**, 16–24.

Nugent K.P., Daniels P., Stewart B., Patankar R. & Johnson C.D. (1999) Quality of life in stoma patients. *Diseases of the Colon and Rectum* **4**, 1569–1574.

O'Connor G. (2005) Teaching stoma-management skills: the importance of self-care. *British Journal of Nursing* **14**, 320–324.

Peng J., Shi D., Goodman K.A., Goldstein D., Xiao C., Guan Z. & Cai S. (2011) Early results of quality of life for curatively treated rectal cancers in Chinese patients with EORTC QLQ-CR29. *Radiation Oncology* **6**, 93.

Pritchard M.J. (2011) Using the Hospital Anxiety and Depression Scale in surgical patients. *Nursing Standard* **25**, 35–41.

Raingruber B. (2011) The effectiveness of psychosocial interventions with cancer patients: an integrative review of the literature (2006–2011). *ISRN Nursing* **638218**, 1–27.

Rehse B. & Pukrop R. (2003) Effects of psychosocial interventions on quality of life in adult cancer patients: meta analysis of 37 published controlled outcome studies. *Patient Education and Counseling* **50**, 179–186.

Research Randomizer (2014) Retrieved from www.randomizer.org/ on 12 May 2014.

Ross L., Abild-Nielsen A.G., Thomsen B.L., Karlsen R.V., Boesen E.H. & Johansen C. (2007) Quality of life of Danish colorectal cancer patients with and without a stoma. *Supportive Care in Cancer* **15**, 505–513.

Seaward B.L. (2006) *Stress Management: Principles and Strategies for Health and Well-being*, 5th edn. Jones & Bartlett, Boston, MA.

Shah P. (2011) Intention-to-treat and per-protocol analysis. *Canadian Medical Association Journal* **183**, 696.

Silva M.A., Ratnayake G. & Deen K.I. (2003) Quality of life of stoma patients: temporary ileostomy versus colostomy. *World Journal of Surgery* **27**, 421–424.

Simmons K.L., Smith J.A., Bobb K. & Liles L.L.M. (2007) Adjustment to colostomy: stoma acceptance, stoma care self-efficacy and interpersonal relationships. *Journal of Advanced Nursing* **60**, 627–635.

Stuifbergen A., Becker H., Blozis S., Beal C. & Park I. (2008) Conceptualization and development of the acceptance of Chronic Health Conditions Scale. *Issues in Mental Health Nursing* **29**, 101–114.

Till J.E., NcNeil B.J. & Bush R.S. (1984) Measurement of multiple components of quality of life. *Cancer Treatment Symposium* **1**, 177–181.

Von Ah D., Storey S., Jansen C.E. & Allen D.H. (2013) Coping strategies and interventions for cognitive changes in patients with cancer. *Seminars in Oncology Nursing* **29**, 288–299.

White C. (1997) Psychological factors in postoperative adjustment to stoma surgery. *Annals of the Royal College of Surgeons of England* **79**, 3–7.

Williams J. (2008) Flatus, odour and the ostomist: coping strategies and interventions. *British Journal of Nursing* **17**, S10.

Williams J. (2012) Stoma care: intimacy and body image issues. *Practice Nursing* **23**, 91–93.

Wilson T.R., Alexander D.J. & Kind P. (2006) Measurement of health-related quality of life in the early follow-up of colon and rectal cancer. *Diseases of the Colon and Rectum* **49**, 1692–1702.

Worster B. & Holmes S. (2008) The preoperative experience of patients undergoing surgery for colorectal cancer: a phenomenological study. *European Journal of Oncology Nursing* **12**, 418–424.

Wu H.K.-M., Chau J.P.-C. & Twinn S. (2007) Self-efficacy and quality of life among stoma patients in Hong Kong. *Cancer Nursing* **30**, 186–193.

Zigmond A.S. & Snaith R.P. (1983) The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica* **67**, 361–370.

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