DR LIM SIEW HOON (Orcid ID : 0000-0002-7189-0333)

DR HONG-GU HE (Orcid ID : 0000-0001-8545-1123)

Article type : Original Research: Clinical Trial

Descriptive title: Pilot Trial of a STOMA psychosocial intervention programme for colorectal cancer patients with stomas

Siew Hoon LIM, PhD, RN

Senior Staff nurse, Division of Nursing, Singapore General Hospital, Singapore;

Alice Lee Centre for Nursing Studies, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

Level 2, Clinical Research Centre, Block MD11

10 Medical Drive, Singapore 117597

Tel.: +65 91802031; E-mail: lim.siew.hoon1@sgh.com.sg

Sally Wai Chi CHAN, PhD, RN

Professor and Head, School of Nursing and Midwifery, Faculty of Health and Medicine,

The University of Newcastle, Australia

Tel: +61 2 4921 6770; E-mail: sally.chan@newcastle.edu.au

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/jan.13973

Aloysius CHOW, Bsc (Hons)

Research Collaborator, Alice Lee Centre for Nursing Studies, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

Tel.: +65 6516 7448; Email: chow.aloysius@gmail.com

Lixia ZHU, PhD, RN

Research Collaborator, Alice Lee Centre for Nursing Studies, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

Tel.: +65 9467 5708; Email: nurzl@nus.edu.sg

Jiunn Herng LAI, MBBS, M. Med (Surgery), FRCSEd

Director and Consultant Surgeon, Mount Elizabeth Hospital, Singapore

Tel: +65 6737 0027; E-mail: lai@drlaijh.com

Hong-Gu HE, PhD, MD, RN

Assistant Professor, Alice Lee Centre for Nursing Studies, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

Tel.: +65 6516 7448; Email: nurhhg@nus.edu.sg

CORRESPONDING AUTHOR:

Siew Hoon LIM, PhD, RN

Senior Staff nurse, Division of Nursing, Singapore General Hospital, Singapore;

Alice Lee Centre for Nursing Studies, Yong Loo Lin School of Medicine, National University of Singapore, Singapore

Level 2, Clinical Research Centre, Block MD11

10 Medical Drive, Singapore 117597

Tel.: +65 91802031; E-mail: lim.siew.hoon1@sgh.com.sg

ACKNOWLEDGEMENTS

We thank the Singapore Cancer Society for providing generous funds for this study. We also appreciate Singapore General Hospital for allowing access to patients. We thank the nurses of Singapore General Hospital for providing support for this study, especially Senior Nurse Clinician Ong Choo Eng for her expert advice. the We thank the National University Health System Medical Publications Support Unit for the assistance in the language editing of this manuscript.

CONFLICT OF INTEREST STATEMENT

No conflict of interest has been declared by the authors.

FUNDING STATEMENT

This study is funded by Singapore Cancer Society (SCS) Cancer Research Grant 2013.

AUTHOR CONTRIBUTIONS:

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE*):

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

2) drafting the article or revising it critically for important intellectual content.

* https://imsva91-ctp.trendmicro.com:443/wis/clicktime/v1/query?url=http%3a%2f%2fwww.icmje.org%2frecommendations%2f&umid=B6CED703-80D1-CC05-834B-F283FD157A91&auth=6e3fe59570831a389716849e93b5d483c90c3fe4-6fff9680d1a9ec9d5503d89a40976c1bed164df8

ABSTRACT

Aims. To evaluate preliminary effects of a newly developed STOMA psychosocial intervention programme that was delivered via a multi-modal and multi-dimensional approach on the improvement of outcomes of colorectal cancer patients with stoma.

Background. With a distorted body image and the loss of an essential body function, stoma patients face difficulties in everyday life in terms of physical, psychological and social aspects. Few studies have explored effects of psychosocial interventions on improving stoma-related health outcomes.

Design. This was a two-group pre-test-post-test pilot randomised controlled trial.

Methods. Fifty-three participants were recruited from July 2015 - November 2016 in a tertiary public hospital in Singapore. They were randomised into either intervention group (N = 29) or control group (N = 24). Stoma care self-efficacy, acceptance of stoma, stoma proficiency, length of hospital stay, anxiety and depression and quality of life were measured. IBM SPSS 24.0 was used to analyse the data.

Results. There was an improvement in acceptance of stoma in the intervention group ($p < 0.05$). Significant effects on stoma care self-efficacy, stoma proficiency, length of hospital stay, anxiety and depression level and quality of life were not shown.

Conclusion. This study developed a feasible and applicable psychosocial intervention programme and generated preliminary evidence in the positive outcomes of colorectal cancer patients with stoma. Future studies can explore technology-based interventions to provide a more sustainable support for patients with stoma.

Trial registration no.: ISRCTN41915584.

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

BACKGROUND

Colorectal cancer patients undergoing stoma formation in the treatment process face with significant impacts on their physical, cognitive, emotional and social functions (Da Silva et al., 2012; Notter & Chalmers, 2012). It is often challenging for stoma nurse specialists to carry out holistic pre-

operative nursing assessments, provide counselling according to individual needs and begin stoma education within the short time frame between the diagnosis and the surgery required for colorectal cancer. Confounding issues are related to information seeking and managing fear and anxiety as they cope with their cancer diagnosis and treatment options pre-operatively (Xu, Pan, & Lin, 2016). Assisting patients in the acceptance of their stoma is essential as acceptance is closely linked to their adjustment and eventual self-efficacy in stoma care (Simmons et al., 2007). Patient reliance and a lack of proficiency in self-care of stoma resulting in managing issues on discharge have been common challenges to (Chaudhri et al., 2005; Lim et al., 2013).

Interpersonal relationships are important in helping one to reintegrate successfully in the society when living with a stoma (Simmons et al., 2007). Family members have been commonly involved to enhance the effectiveness of interventions on patient outcomes in cancer patients (Griffin et al., 2014). Patients with poor interpersonal relationships tend to have poor stoma acceptance and reduced self-efficacy in stoma care (Bekkers et al., 1996; Simmons et al., 2007). Equipping patients and their families with required knowledge and tools pre-operatively is therefore essential to assist in their coping with the stoma in the post-operative rehabilitation period.

Psychosocial interventions are widely regarded as valuable adjuncts to medical treatments of cancer for patients who are experiencing constant psychological distress (Raingruber, 2011). The benefits of psychosocial interventions (e.g. educational interventions, cognitive-behavioural therapy and supportive group therapy) include provision of support in emotional and social aspects from self-care and psychoeducational interventions as well as assisting patients in reducing fatigue, depression and anxiety and improving social relationships and overall quality of life (QoL) (Carlson et al., 2004; Raingruber, 2011). However, there is a paucity of studies that examine the provision of specific interventions for colorectal cancer patients with stoma (Lim et al., 2013).

THE STUDY

Aims

This study aimed to evaluate the preliminary effects of a STOMA psychosocial intervention programme on the outcomes of colorectal cancer patients with a newly formed stoma.

Hypotheses

Compared with patients in the control group, those in the intervention group will report statistically and significantly higher levels of stoma care self-efficacy, acceptance of stoma and stoma proficiency, shorter lengths of hospital stay, lower levels of anxiety and depression and improved QoL.

Design/Methodology

This was a two-group pre-test-post-test pilot randomised controlled trial (RCT). The research assistants (AC & ZLX) who collected the mid-intervention data and post-intervention data were blinded from group allocation, which was conducted by the first author (LSH). The details of study design can be found in the study protocol (Lim et al., 2015).

Intervention

In the Singaporean context, the routine stoma care is provided both pre-operatively, during admission and within five days post-operatively. Stoma siting is carried out by a stoma nurse specialist pre-operatively. Stoma education typically starts three to five days post-operatively. Patients will learn and carry out return demonstrations to the stoma nurse specialist where they will be observed by the nurse in their demonstration of stoma appliance change. If deemed not proficient, patients will return after discharge for another teaching session.

Participants allocated to the control group received routine care, whereas those in the intervention group received routine care and the STOMA psychosocial intervention (Lim et al., 2015). The theoretical framework of the STOMA psychosocial intervention programme (Lim et al., 2015) was built on Bandura's self-efficacy theory (1977) and the stoma acceptance conceptual framework by Simmons et al. (2007). The programme integrated a multi-modal and multi-dimensional approach, which included a pre-operative individual face-to-face psychoeducational session, an educational booklet provided and five telephone follow-ups (one pre-operatively and four post-operatively) by the first author (LSH) who is a nurse with experience in colorectal nursing.

Participants

Participants were recruited from both inpatient and outpatient settings of a tertiary public hospital in Singapore from July 2015 - November 2016. Patients who were undergoing elective colorectal resections, which required formation of a stoma were recruited (Lim et al., 2015). Those who had surgical complications that led to a delay of more than five days before attaining stoma proficiency post-operatively were excluded. After the baseline data collection, participants were randomly assigned based on the randomized list generated by the Research Randomizer (2014).

The study was designed to be a full RCT, with a plan to recruit 84 participants based on the power analysis (Lim et al., 2015). However, there was a large number of patients who rejected to participate in the study (N = 20) or did not meet the selection criteria (N = 33) during the funded time-period in the participating hospital. Thus, the recruitment stopped at 53 participants. Therefore, this study was considered a pilot RCT.

Outcome measures

Stoma care self-efficacy, acceptance of stoma, stoma proficiency, length of hospital stay, and anxiety and depression and QoL were measured. The details are reported in the Consolidated Standards of Reporting Trial flow chart in the study protocol (Lim et al., 2015). Patients' demographic and clinical details and length of stay were collected through review of participants' medical records and self-reports (Lim et al., 2015).

Data collection

Eligible patients were identified by the research assistant (AC) at the clinic when they were newly diagnosed and scheduled for operations. Written consent was obtained from those who agreed to participate. Baseline data (T1) were collected immediately thereafter. The first author (LSH) then called each patient and randomly allocated him/her to the intervention or control group. The research assistants (AC and ZLX), who were blinded to group allocation, collected T2 data (day of discharge) in the ward and T3 (one month on discharge) and T4 (four months on discharge) data via face-to-face interviews at a place that was most convenient for each patient, such as in an outpatient specialist clinic or in patient's home.

Ethical considerations

Ethical approval was obtained from the Institutional Review Board of the study hospital. A participant information sheet with study details was provided and written consent was sought. Voluntary participation and the anonymity of patient details were ensured. This study was registered with BioMed Central Ltd. (Registration no.: ISRCTN41915584).

Data analysis

IBM SPSS for Windows Version 24.0 (IBM Corp., Armonk, NY) was used. Descriptive statistics were used to report participants' sociodemographic, clinical data and levels of baseline outcomes. Mann-Whitney U test was used to analyse length of hospital stay, stoma proficiency, anxiety and depression. Wilcoxon Signed Rank test was used to compare within group differences for both anxiety and depression. Taking into consideration of the baseline variables of anxiety and depression, normalization method was used. Percentage changes were calculated for each timepoint from baseline scores. The anxiety and depression baseline scores were normalized to zero before further data analysis was carried out, which is a common method used in statistics for testing of hypothesis (Hughes et al., 2002).

Univariate analysis of covariance (ANCOVA) using general linear model was conducted to compare the other four outcomes, including stoma care self-efficacy, acceptance of stoma and QoL between two groups at each timepoint. Repeated measures ANCOVA was carried out to examine the difference of the same four outcomes between groups over time. Demographics and baseline scores were adjusted. Statistical significance was set at $p < 0.05$.

Validity and reliability

The contents of the intervention were developed and cross-examined by an expert panel, including an experienced stoma care nurse clinician, a colorectal surgeon and an academic assistant professor (Lim et al., 2015). All instruments used were tested for reliability and validity in other studies. Randomisation of participants into two groups and allocation concealment were achieved. The research assistants who collected data were blinded to the allocation status of the participants to avoid bias. The same researcher (LSH) conducted the face-to-face psychoeducational session and all telephone sessions for all patients in the intervention group.

RESULTS

Among the 116 patients who were screened for eligibility, 53 (45.7%) were recruited. During the study process, one participant passed away and one participant did not receive the intervention due to inconvenience and, thus, they were excluded from the data analysis. The Consolidated Standards of Reporting Trials flowchart is shown in Figure 1. Participants' sociodemographic and clinical characteristics and baseline anxiety and depression levels between groups are reported in Table 1.

Comparison of outcome variables between groups at each timepoint and between groups over time

Stoma care self-efficacy

There was no significant group difference in stoma care self-efficacy at T2 (F = 0.75, p = 0.70), T3 (F = 1.56, p = 0.15) and T4 (F = 0.89, p = 0.57) (Table 2). There was no difference of the self-efficacy found between two groups and no time effect. There was no difference of the scores found between two groups over 3 time points either. The profile plot showed an overall greater increase of self-efficacy in intervention group, especially at T4 (Figure 2).

Acceptance of stoma

Table 2 shows significant group differences in acceptance of stoma at T3 (F = 2.17, p = 0.003) and T4 (F = 8.42, p = 0.006) but not at T2 (F = 0.71, p = 0.74). A significant group effect (F = 13.67, p < 0.001) were found (Table 2). The profile plot showed an overall higher level of acceptance in intervention group (Figure 2).

Stoma proficiency

The median and interquartile range (IQR) of days to stoma proficiency in the intervention and control groups were 4 (2 - 6) and 3 (2 - 4.75), respectively. The results showed non-significant differences (Z = -1.24, p = 0.22) between groups.

Length of hospital stay

The IQR of length of hospital stay in the intervention and control groups were 9 (6 - 14) and 7 (6 - 8), respectively. The results revealed non-significant differences between the two groups (Z = -1.50, p = 0.13). Seven participants in the intervention group had wound complications and other medical conditions including urinary tract infections and sepsis. Three participants in the control group had wound and stoma-related complications.

Anxiety and depression

The mean difference in percentage change of anxiety scores between groups at T2 (37.73%), T3 (8.49%) and T4 (13.48%) were not statistically significant. The mean difference in percentage change of depression scores between groups at T2 (131.59%), T3 (94.32%) and T4 (17.57%) were not statistically significant either (Table 2). Only a statistically significant difference in anxiety scores within intervention group (p = 0.01) from T3 to T4 was found. No significant difference in depression scores were found in the within group comparisons. The graphical representation showed overall reduction in the level of anxiety and depression in both groups from T2 to T4 (Figure 2).

QoL

There were no significant group differences in QoL at T2 (F = 1.16, *p* = 0.35), T3 (F = 1.37, *p* = 0.22) and T4 (F= 1.57, *p* = 0.14) (Table 2). There was no group effect between the intervention and control group, time effect and time effect between groups. The profile plot showed an overall improvement in the quality of life in both groups from T2 to T4 (Figure 2).

DISCUSSION

This study evaluated preliminary effects of a STOMA psychosocial intervention programme on newly diagnosed colorectal cancer patients with newly formed stoma in Singapore. Participants in both groups had increasing self-efficacy scores, but the findings showed no significant differences in the levels of stoma care self-efficacy at each timepoint, although the intervention group reported higher scores. The multi-dimensional approach used in the STOMA programme included health education, skills learning, mastery experience, role modelling and persuasion with verbal cues. These strategies were consistent to a previous study that used self-efficacy enhancing interventions for colorectal cancer patients which showed significant improvement in self-efficacy (Zhang et al., 2014).

The findings in this study reported significant differences in the levels of acceptance, with higher scores in the intervention group. Our programme helped to improve patients' acceptance levels through various strategies, including encouraging positive attitude and family support, sharing positive coping skills and common concerns of undergoing stoma formation surgery and post-operative adjustment with stoma (Chao et al., 2010; Lim et al., 2015).

Participants in the intervention group obtained higher levels of stoma proficiency, although there were no significant group differences. Unlike the two studies (Chaudhri et al., 2005; Bryan & Dukes, 2010), many participants in this current study expressed that they did not empty and change their stoma pouch appliances by themselves during hospitalisation as they sought for assistance by nurses and stoma nurse specialists most of the time. The stoma education protocol can be used as a

convenient and standardised tool in ward settings for nurses to encourage greater involvement of patients in achieving stoma care proficiency.

There were no significant group differences in length of hospital stay, which is not consistent with the findings from previous studies that measured length of hospital stay in colorectal patients with stomas, requiring further investigation (Chaudhri et al., 2005; Bryan & Dukes, 2010).

The effect of current intervention programme in improving the outcome of anxiety and depression was not conclusive in this study and warrants further exploration. According to Jacobsen and Jim (2008), the estimates of the prevalence of anxiety and depression in patients with cancer varied broadly, which led to the question whether anxiety and depression should be assessed in terms of an individual symptom approach, multi-symptom approach, or even as a clinical syndrome.

There were no significant differences in QoL, although the intervention group reported higher scores, which may be explained by the gradual decrease of concerns over the four-month after discharge. Patients demonstrated improved QoL only at six months compared with one month post-operatively (Carlsson et al., 2010).

Limitations and recommendations for future studies

This study had some limitations. Firstly, the study only recruited English and Chinese speaking patients; thus, the results in this study may not be generalizable to patients who do not speak these two languages. Secondly, this study was unable to reach the target sample size of 84 patients as a large number of patients were not eligible based on the selection criteria (Figure 1). It was recommended to conduct clinical trial feasibility to identify potential challenges to provide a more practical assessment of the optimum timelines, targets and cost required to complete the project objectives (Rajadhyaksha, 2010). A group of patients refused in participation due to the effort required in travelling to attend the session, an alternative option in future is to develop a mobile

application so they can benefit from the intervention in the most convenient manner, with support from their caregivers.

The sample size of this study was small and conducted in Asian context, which limited the generalizability of the study results. An adequate sample size is vital to determine acceptable clinical differences between groups in a study (Chan, 2003). Further investigation in a full-scale RCT is warranted in the Western context to determine effects of the intervention on stoma care self-efficacy, stoma proficiency, length of hospital stay, anxiety and depression level and quality of life. In addition, this study only measured short-term effects of the intervention. Future studies with technology-based interventions and follow-ups of up to 12 months are essential to explore the long-term effects of the programme.

CONCLUSION

The STOMA psychosocial intervention programme was the first study of its kind that placed a primary emphasis on promoting stoma self-care efficacy in patients with colorectal cancer as well as acceptance of stoma, psychological wellbeing and QoL post-operatively. Our pilot results suggest that this programme has the potential to improve the outcomes of colorectal cancer patients with stoma, which requires further exploration in future full-scale studies.

REFERENCES

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

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.

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

Carlson, L., Angen, M., Cullum, J., Goodey, E., Koopmans, J., Lamont, L., & Robinson, J. (2004). High levels of untreated distress and fatigue in cancer patients. *British Journal of Cancer, 90*(12), 2297-2304.

Carlsson, E., Berndtsson, I., Hallén, A.-M., Lindholm, E., & Persson, E. (2010). Concerns and quality of life before surgery and during the recovery period in patients with rectal cancer and an ostomy. *Journal of Wound Ostomy & Continence Nursing, 37*(6), 654-661.

Chan, Y. H. (2003). Randomised controlled trials (RCTs)-sample size: the magic number?. *Singapore Medical Journal*, *44*(4), 172-174.

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.

Da Silva, A. L., Faustino, A. M., & Oliveira, P. G. D. (2012). The sexuality of the patient with intestinal ostomy: Literature review. *Journal of Nursing UFPE, 7*(3), 879-887.

Griffin, J. M., Meis, L. A., MacDonald, R., Greer, N., Jensen, A., Rutks, I., & Wilt, T. J. (2014). Effectiveness of family and caregiver interventions on patient outcomes in adults with cancer: A systematic review. *Journal of general internal medicine*, *29*(9), 1274-1282.

Hughes, A. R., Kirk, A. F., Mutrie, N., & MacIntyre, P. D. (2002). Exercise consultation improves exercise adherence during phase iv cardiac rehabilitation. *Medicine & Science in Sports & Exercise, 34*(5), 183.

Jacobsen, P. B., & Jim, H. S. (2008). Psychosocial interventions for anxiety and depression in adult cancer patients: Achievements and challenges. *CA: A Cancer Journal for Clinicians, 58*(4), 214-230.

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, S. W. C., Lai, J. H., & He, H. G. (2015). A randomized controlled trial examining the effectiveness of a STOMA psychosocial intervention programme on the outcomes of colorectal patients with a stoma: study protocol. *Journal of advanced nursing*, *71*(6), 1310-1323.

Notter, J., & Chalmers, F. (2012). Living with a colostomy: A pilot study. *Gastrointestinal Nursing, 10*(6), 16-24.

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

Rajadhyaksha V. Conducting Feasibilities in Clinical Trials: An Investment to Ensure a Good Study. *Perspectives in Clinical Research*. 2010;1(3):106-109.

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

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.

Xu, L., Pan, Q., & Lin, R. (2016). Prevalence rate and influencing factors of preoperative anxiety and depression in gastric cancer patients in China: Preliminary study. *Journal of International Medical Research*, *44*(2), 377-388.

Zhang, M., Chan, S. W., You, L., Wen, Y., Peng, L., Liu, W., & Zheng, M. (2014). The effectiveness of a self-efficacy-enhancing intervention for Chinese patients with colorectal cancer: A randomized controlled trial with 6-month follow up. *International Journal of Nursing Studies, 51*(8), 1083-1092.

Table 1 Participants' sociodemographic, clinical characteristics, and baseline data between groups (n = 51)

	Total (n = 51) n (%)	**Intervention (n = 27)** n (%)	**Control (n = 24)** n (%)
Age (years):			
Range	21-88	21-88	33-86
Mean (SD)	63.0 (13.2)	63.5 (13.3)	62.3 (13.4)
Gender			
Male	33 (64.7)	16 (59.3)	17 (70.8)
Female	18 (35.3)	11 (40.7)	7 (29.2)
Marital status			
Married	28 (54.9)	15 (55.6)	13 (54.2)
Other[†]	23 (45.1)	12 (44.4)	11 (45.8)
Ethnicity			
Chinese	43 (84.3)	23 (85.2)	20 (83.3)
Malay	4 (7.85)	3 (11.1)	1 (4.2)
Others	4 (7.85)	1 (3.7)	3 (12.5)
Education level[a]			
No formal education	4 (7.8)	2 (7.4)	2 (8.3)
Primary school	21 (41.2)	12 (44.4)	9 (37.5)
Secondary school	12 (23.5)	6 (22.2)	6 (25.0)
ITE/Polytechnic/Juni or college/University	14 (27.5)	7 (25.9)	7 (29.2)
Employment status			
Employed	23 (45.1)	12 (44.4)	11 (45.8)
Unemployed	28 (54.9)	15 (55.6)	13 (54.2)
Staying with			
Spouse	32 (62.7)	17 (63.0)	15 (62.5)
Children	11 (21.6)	4 (14.8)	7 (29.2)
Others[‡]	8 (15.7)	6 (22.2)	2 (8.3)
Caregiver			
Spouse	20 (39.2)	9 (33.3)	11 (45.8)
Children	14 (27.5)	7 (25.9)	7 (29.2)
Others[‡]	17 (33.3)	11 (40.7)	6 (25.0)
Diagnosis			
Rectal cancer	41 (80.4)	23 (85.2)	18 (75.0)
Sigmoid cancer	7 (13.7)	3 (11.1)	4 (16.7)
Recto sigmoid cancer	3 (5.9)	1 (3.7)	2 (8.3)
Types of stoma			
Ileostomy	25 (49.0)	16 (59.3)	9 (37.5)
Colostomy	26 (51.0)	11 (40.7)	15 (62.5)
Stoma status			
Permanent	14 (27.5)	5 (18.5)	9 (37.5)
Temporary	37 (72.5)	22 (81.5)	15 (62.5)
Types of operation			
Anterior resection	31 (60.8)	19 (70.4)	12 (50.0)
Abdominoperineal resection	13 (25.5)	5 (18.5)	8 (33.3)
Others	7 (13.7)	3 (11.1)	4 (16.7)

Past medical history			
Yes	29 (56.9)	17 (63.0)	11 (45.8)
No	22 (43.1)	10 (37.0)	13 (54.2)
Baseline outcome (T1)	**Total (n = 51) Mean (SD)**	**Intervention (n = 22) Mean (SD)**	**Control (n = 21) Mean (SD)**
HADS- Anxiety	4.75 (3.72)	3.56 (3.14)	6.08 (3.92)
HADS- Depression	3.20 (3.63)	1.67 (2.13)	4.92 (4.20)

Note: [†]including single, divorced, and widowed statuses; [‡]including domestic helpers, siblings, and alone/own self; HADS: Hospital Anxiety and Depression Scale; [a]Primary school (aged 7 to 12), Secondary school (aged 13 to 16), ITE/Polytechnic/Junior College/University (aged 17 to 24)

Table 2 Comparison of outcomes between the intervention and control groups at each timepoint as well as between group over time (n = 51)

Outcome variable		Intervention (I) Mean (SD) (n = 27)	Control (C) Mean (SD) (n = 24)	Mean difference (I-C)	F (*p*-value) [a]	95% Confidence interval for difference	Group effect F *(p)*	Time effect F (p)	Time* group interaction effect F (*p*)
Stoma care self-efficacy	T2 Mean (SD), Range	65.70 (16.95), 34 - 107	64.71(16.70), 39 - 101	0.99	0.75 (0.70)	-12.34 to 12.57	3.28 (0.08)	0.18 (0.68)	1.74 (0.20)
	T3 Mean (SD), Range	80.52 (12.78), 52 - 105	76.46 (16.68), 50 - 97	4.06	1.56 (0.15)	-3.55 to 16.48			
	T4 Mean (SD), Range	87.19 (14.25), 54 - 107	77.42 (12.54), 52 - 100	9.77	0.89 (0.57)	-1.50 to 19.62			
Acceptance of stoma	T2 Mean (SD), Range	33.44 (6.35), 23 - 48	31.17 (5.15), 21 - 41	2.27	0.71 (0.74)	-2.96 to 6.03	13.67 (<0.001)*	0.58 (0.45)	0.70 (0.41)
	T3 Mean (SD), Range	36.04 (5.75), 24 - 46	31.92 (4.17), 24 - 40	4.12	2.17 (0.03)*	0.57 to 7.62			
	T4 Mean (SD), Range	39.67 (5.12), 30 - 48	35.50 (5.05), 26 - 44	4.17	1.32 (0.25)	0.52 to 8.41			
QoL	T2 Mean (SD), Range	38.48 (7.69), 27 - 55	39.04 (5.09), 31 - 50	-0.56	1.16 (0.35)	-4.26 to 4.75	3.41 (0.07)	0.32 (0.58)	0.23 (0.64)
	T3 Mean (SD), Range	33.59 (4.72), 27 - 45	36.58 (7.09), 37 - 52	-2.99	1.37 (0.22)	-7.86 to 0.85			
	T4 Mean (SD), Range	31.59 (3.79). 27 - 43	33.54 (4.26), 27- 41	-1.95	1.57 (0.14)	-4.50 to 1.05			

Outcome variable	T1 Mean (SD)		T2 Mean (SD), Mean % Change		T2 Mean % Change group difference		T3 Mean (SD), Mean % Change		T3 Mean % Change group difference		T4 Mean (SD), Mean % Change		T4 Mean % Change group difference		T2 to T3 Within-subjects time effect *Z* (*p*)		T3 to T4 Within-subjects time effect *Z* (*p*)		T2 to T4 Within-subjects time effect *Z* (*p*)	
	I (n =27)	C (n = 24)	I (n = 27)	C (n = 24)	Mean	Z (*p*)	I (n = 27)	C (n=24)	Mean	Z (*p*)	I (n = 27)	C (n = 24)	Mean	Z (*p*)	I (n = 27)	C (n = 24)	I (n = 27)	C (n = 24)	I (n = 27)	C (n = 24)
Anxiety[b,c]	3.56 (3.14)	6.08 (3.92)	2.00 (2.13), -43.82	5.71 (3.98), -6.09	-37.73	1.60 (0.11)	2.04 (1.83), -42.70	4.00 (3.80), -34.21	-8.49	0.21 (0.84)	1.30 (1.79), -63.48	3.04 (2.63), -50	-13.48	0.78 (0.43)	0.60 (0.55)	-1.65 (0.10)	**-2.45 (0.01*)**	-0.78 (0.43)	-1.79 (0.07)	-2.11 (0.04)
Depression[b,d]	1.67 (2.13)	4.92 (4.20)	4.56 (3.83), 173.05	6.96 (5.00), 41.46	131.59	-0.72 (0.47)	3.33 (2.77), 99.40	5.17 (3.95), 5.08	94.32	-1.67 (0.09)	1.78 (2.78), 6.59	4.38 (3.92), -10.98	17.57	0.11 (0.92)	-1.58 (0.12)	-0.89 (0.37)	-1.99 (0.05)	0.38 (0.71)	-2.37 (0.02)	-0.83 (0.41)

Note: Baseline (T1), Mid-intervention (T2), Post-intervention measurement 1 (T3), Post-intervention measurement 2 (T4); [a]GLM univariate covariate analysis adjusted for age, gender, marital status, ethnicity, education level, employment status, staying with status, presence of caregiver, diagnosis, types of stoma, stoma status, types of operation, and presence of medical history; [b]Formula to calculate the percentage: T2 mean percentage change = (T2-T1)/T1*100, similar for T3 and T4; Percentage change (% change); Intervention (I); Control (C); Wilcoxon signed rank tests were used to perform within group comparisons for mean % change with Bonferroni corrected whereas Mann-Whitney U tests were used to compare the group differences of mean percentage changes; [c]Median and interquartile range (IQR) of anxiety in intervention group at

T1 Baseline (4, 0-6), T2 (1, 0-3), T3 (1, 0-4), and T4 (1, 0-2) and control group at T1 (5, 3-9), T2 (5, 2.25-8), T3 (2, 1-6), and T4 (2, 1-5.50); [d]Median and interquartile range (IQR) of depression in intervention group at T1 (1, 0-2), T2 (3, 1-7), T3 (3, 1-6), and T4 (1, 0-2) and control group at T1 (5, 1.25-7), T2 (550, 3.25-10.50), T3 (5, 2-8), and T4 (3.50, 1-6.75); *Significant at $p < 0.05$.

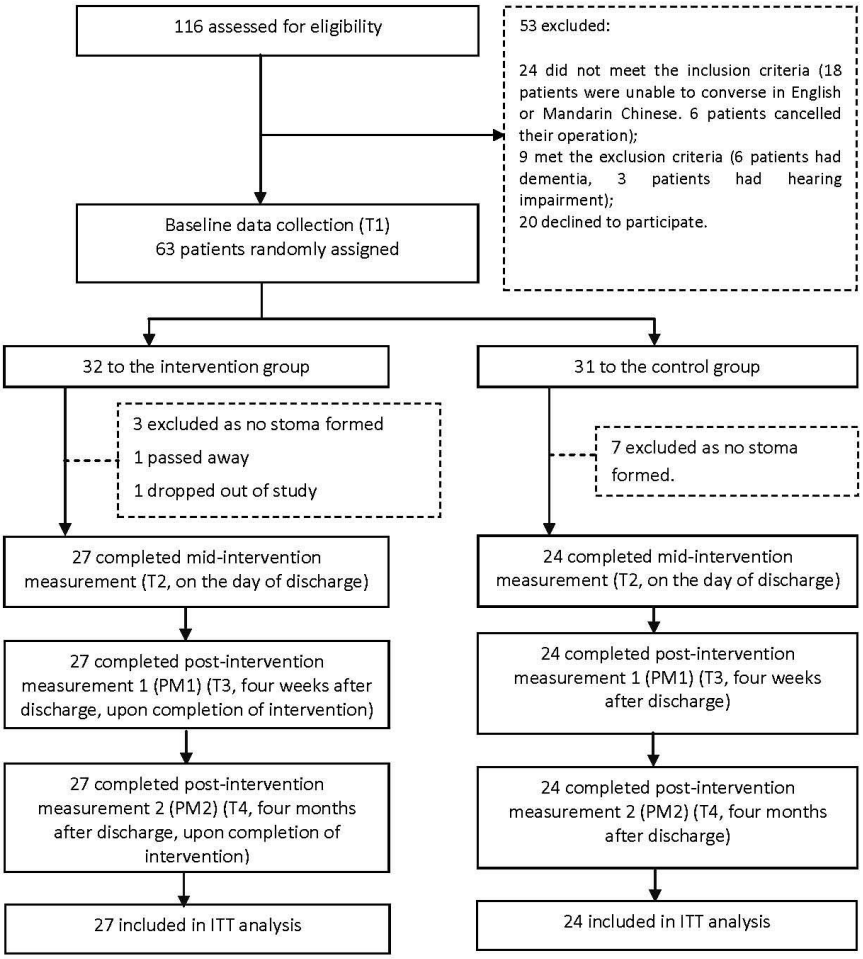
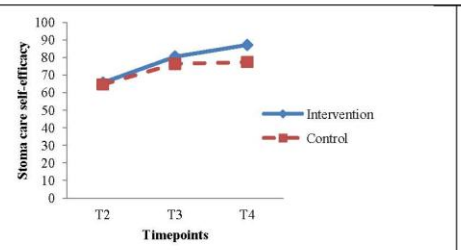
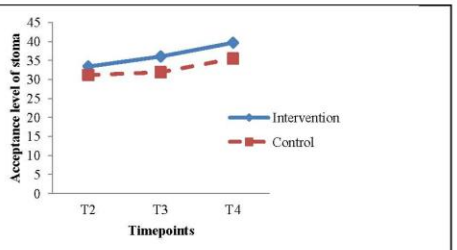


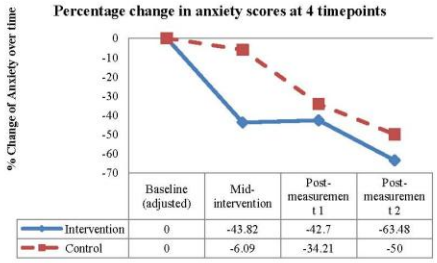
Figure 1 CONSORT flowchart



Profile plot of stoma care self-efficacy mean scores across three timepoints: T2, T3, and T4

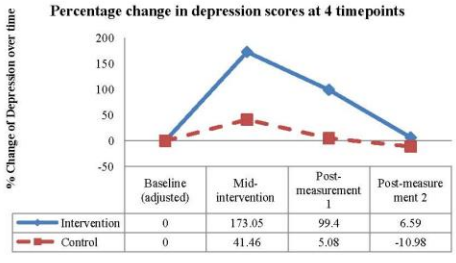


Profile plot of acceptance level of stoma mean scores across three timepoints: T2, T3, and T4



	Baseline (adjusted)	Mid-intervention	Post-measurement 1	Post-measurement 2
Intervention	0	-43.82	-42.7	-63.48
Control	0	-6.09	-34.21	-50

Percentage change in anxiety scores from baseline to post-intervention measurement timepoint



	Baseline (adjusted)	Mid-intervention	Post-measurement 1	Post-measurement 2
Intervention	0	173.05	99.4	6.59
Control	0	41.46	5.08	-10.98

Percentage change in depression scores from baseline to post-intervention measurement timepoint

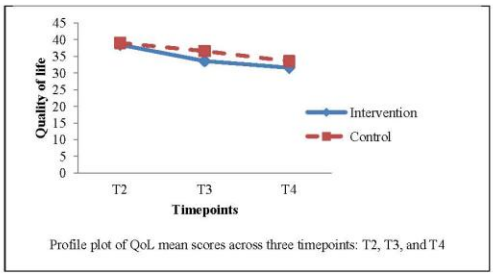


Figure 2 Profile plots of the outcome measures