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A randomised controlled trial examining the effectiveness of a STOMA psychosocial intervention programme on the outcomes of colorectal patients with a stoma

Submission date
04/07/2014

Recruitment status
No longer recruiting

Registration date
25/07/2014

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Ileostomy is a procedure where the small intestine is diverted to an opening in the abdomen. The waste products are collected through an opening called a stoma in the tummy. With the loss of an important body function and a distortion in 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 tested psychosocial interventions (methods) on the improvement of patients stoma-related health concerns. The aim is to find out if a psychosocial intervention leads to a significant reduction in days to stoma proficiency, length of hospital stay, anxiety and depression, as well as improvement in their ability to care for themselves, acceptance of the stoma, and quality of life for patients with a newly formed stoma.

Who can participate?
Patients undergoing elective colorectal resections who require formation of a permanent stoma.

What does the study involve?
Eligible patients will be randomly allocated to either a control group or an intervention group. Patients in the control group will receive routine care, where they will receive education on care of stoma after the operation. Patients in the intervention group will receive the STOMA psychosocial intervention programme in addition to routine care. The STOMA psychosocial intervention programme includes an individual psychoeducation face-to-face session (before the operation) with a booklet provided, and five telephone follow-up sessions (one before the operation and four after).

What are the possible benefits and risks of participating?
Patients can receive education and support in the aspects of stoma care which can help in the

improvement of their quality of life. There is no risk or any discomfort for participants in this study. The only inconvenience will be the time spent filling in questionnaires and receiving 1 hour of face-to-face teaching and five 15-minute telephone sessions.

Where is the study run from?
Singapore General Hospital (Singapore).

When is the study starting and how long is it expected to run for?
The study will start in January 2015 and is expected to run for 1 year.

Who is funding the study?
Singapore Cancer Society (Singapore).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
JAN-2014-0582

Study information

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

Study objectives
The hypotheses of this study were set as follows:
1. When compared with the control group, in the short term (on the day of discharge), medium term (one month after discharge) and long term (three months after discharge), patients in the interventional group who receive STOMA psychosocial intervention will report significantly higher levels of self-efficacy in stoma self-care.
2. The patients in the intervention group will demonstrate a significant reduction in time to stoma proficiency.
3. The patients in the intervention group will stay in hospital for a significantly shorter period of time.
4, The patients in the intervention group will report significantly lower levels of anxiety and depression.
5. The patients in the intervention group will report significantly higher levels of acceptance in relation to their stoma.
6. The patients in the intervention group will report a significantly better quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
SingHealth Centralized Institutional Review Board (CIRB), 24/10/2013, ref. 2012/1038/A

Study design
Randomized controlled two-group pretest and repeated posttests single-blind experimental design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Colorectal cancer

Interventions

There are two groups in the study.
1. Control: The participants in the control group will only receive routine care provided by the hospital.
2. Intervention: The participants in the intervention group will receive routine care and STOMA psychosocial intervention. The STOMA psychosocial intervention programme includes an individual psychoeducation face-to-face session (pre-operatively) with booklet provided, and five telephone follow-up sessions (one pre-operatively and four post-operatively). The main contents include:
2.1. An introduction to psychosocial interventions
2.2. 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
2.3. Availability of community resources and support services
2.4. Common issues and concerns in resuming activities post-operatively with a stoma
2.5. A step-by-step guide in stoma care training
2.6. Stoma education protocol to guide participants in setting goals

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome measures is patients' stoma care self-efficacy. The instrument used to measure this outcome is described below:
The Stoma Self-Efficacy Scale consists of 22 items (Cronbachs 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 understand and read Mandarin. This will be measured 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), post-intervention 1 and post-intervention 2.

Secondary outcome measures
The secondary outcome measures are days to stoma proficiency, length of hospital stay, acceptance of stoma, level of anxiety and depression and quality of life. The instruments used to measure these secondary outcomes are described below:
1. 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 the purpose of this study.
2. Medical record review will be used to collect data of the length of post-operative 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.
3. The Acceptance of Chronic Health Conditions Scale (ACHC scale) is used as the measure of acceptance. This scale measures acceptance of chronic health conditions in general. In order 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 measured on a 5-point Likert scale (1 = strongly agree, 5 = strongly disagree). Thus, higher scores

indicate higher levels of acceptance. The Chinese version of the scale will be used for patients who can only understand and read Mandarin.
4. Patients level of anxiety and depression will be assessed using the Hospital Anxiety Depression Scale (HADS). 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. In order to make it a more effective and detailed tool, the scores can been further analysed: a patient scoring 11 or more on either component will be considered at risk of anxiety or depression; a patient scoring 810 will be considered at borderline risk of anxiety or depression. Meanwhile, patients scoring 07 will be within the normal range. The Chinese version of the HADS will be used for patients who can only understand and read Mandarin.
5. 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 the quality of life in patients with stoma. The QLQ-CR29 served to collect information on patients disease-specific symptoms and adverse effects. The module 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 0100 scores using standard EORTC guidelines. A high score indicates worse symptoms. The Chinese version of the questionnaire will be used for patients who can only understand and read Mandarin.

Overall study start date
01/01/2015

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Aged over 21 years
2. Undergoing elective colorectal resections, including both laparoscopic and open procedures that require formation of a permanent stoma
3. Able to read and speak English or Mandarin

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
84

Key exclusion criteria
1. Undergoing emergency operations
2. Having visual and/or hearing impairments
3. Having cognitive impairments/mental disorders identified in their medical records
4. Having any surgical complication leading to a delay of more than five days before attaining stoma proficiency in the post-operative period

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Singapore

Study participating centre
Singapore General Hospital
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Sponsor information

Organisation
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Sponsor type
Charity

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ROR
https://ror.org/00k1zme04

Funder(s)

Funder type
Charity

Funder Name
Singapore Cancer Society (Singapore)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	qualitative results	01/01/2019	17/12/2020	Yes	No