Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Design, Implementation and Evaluation of Preoperative Patient Self-Efficacy Training Program in Ostomy Care

Protocol summary

Study aim
Design, Implementation and Evaluation of Preoperative Patient Self-Efficacy Training Program in Ostomy Care

Design
Clinical trial with control group, with parallel groups, on 80 patients

Settings and conduct
80 patients who are in the colostomy or ileostomy surgery list in the centers affiliated to Shahid Beheshti University of Medical Sciences will be divided into two groups (intervention and control) by simple random allocation method. patients in the intervention group, In addition to training in the usual way, they will also be trained with the ostomt self-efficacy training program before surgery. the patients of the control group only receive education in the usual way, i.e. education after surgery. Demographic questionnaire tools, clinical information questionnaire and stoma self-efficacy scale will be completed by the patients before surgery and one month after surgery.

Participants/Inclusion and exclusion criteria
Inclusion: Age 18 to 65 years, Absence of cognitive or psychological impairment, Ability to communicate, Exclusion: Performing emergency surgery

Intervention groups
Intervention group patients: In addition to training in the usual way, they are also trained with the self-efficacy training program of the ostomy prepared before the surgery. The training session is conducted face-to-face for each patient and, if the patient wishes, with the presence of his family or caregiver. The session will last for 45 minutes in a hospital or clinic by a wound and ostomy nurse within a week before surgery. Patients of the control group only receive education in the usual way, i.e. education after surgery.

Main outcome variables
Ostomy self-efficacy; Hospitalization time; Number of readmissions; Number of emergency visits; The peristomal skin condition

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220731055588N1**
Registration date: **2022-08-09, 1401/05/18**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-09, 1401/05/18**
Update count: **0**

Registration date
2022-08-09, 1401/05/18

Registrant information

Name
ali ali bakhoda

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8865 5379

Email address
ali.baakhoda@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-06, 1401/05/15

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Design, Implementation and Evaluation of Preoperative Patient Self-Efficacy Training Program in Ostomy Care

Public title
Design, Implementation and Evaluation of Preoperative Patient Self-Efficacy Training Program in Ostomy Care
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 65 years Lack of cognitive or mental impairment Ability to verbal communicate
Exclusion criteria:
Performing emergency surgery
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation will be done using a coin toss by an independent researcher. To prepare the randomized list, a coin will be tossed 80 times. If the coin lands on A, it means the intervention group, and if it lands on B, it means the control group. The randomization results will be recorded in a list from 1 to 80 respectively. In order to hide the results from the researcher's view, according to the list, each of the results will be recorded on a sheet and will be placed in a sealed envelope. The list number corresponding to that result will be written on each envelope. After each sample enters the research, the envelopes from 1 to 80 will be opened and the placement of the patient in the intervention or control group will be determined.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Pharmacy, Nursing and Midwifery Faculties of Shahid Beheshti University of Medic
Street address
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, No. 2660, Vali Asr Ave., Niayesh Cross Road, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2022-06-21, 1401/03/31
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1401.060

Health conditions studied

1

Description of health condition studied
Colostomy; Ileostomy; Colon Malignancies
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The ostomy self-efficacy: The Ostomy self-efficacy is equal to the score obtained by the patient in the ostomy self-efficacy questionnaire. The questionnaire has 22 items in a 5-item Likert scale. The questionnaire is in two dimensions includes ostomy care self-efficacy (13 items) and social self-efficacy (9 items). A higher score indicates higher self-efficacy. The lowest score that can be obtained in this tool is 22 and the highest score is 110.
Timepoint
The stoma self-efficacy questionnaire will complete by patients before surgery and one month after surgery.
Method of measurement
The stoma self-efficacy scale was designed and psychometrically evaluated by Beckers et al. (1996). The questionnaire has 22 items in two dimensions, including ostomy care self-efficacy (first 13 items) and social self-efficacy (next 9 items). Using a Likert scale, the answers are defined from not sure at all (score 1) to completely sure (score 5). A higher score indicates greater ostomy self-efficacy. The lowest score that can be obtained in this tool is 22 and the highest score is 110.

Secondary outcomes

1

Description
Hospitalization time
Timepoint
One month after surgery
Method of measurement

Clinical records and patient interview

2

Description
The number of readmissions
Timepoint
One month after surgery
Method of measurement
Clinical records and patient interview

3

Description
The number of emergency visits
Timepoint
One month after surgery
Method of measurement
Clinical records and patient interview

4

Description
Peristomal skin condition
Timepoint
One month after surgery
Method of measurement
DET ostomy skin tool

Intervention groups

1

Description
Intervention group: (Pre-surgery training In addition to usual training) The patients who are allocated in the intervention group will be invited to participate in an ostomy care training session within one week before surgery in the one of clinic visit sessions or during hospitalization. A training session for 45 minutes will be held in the hospital or clinic for each patient independently. The researcher along with a wound and ostomy nurse will lead the training session. The goals of the training session will include a) familiarizing the patient with the educational content at the level of cognitive perception and b) the ability to change the ostomy bag and take care of the skin around the ostomy at the level of imitation of the psychomotor domain. Educational content will be presented to patients by using lectures, practical simulation of ostomy bag replacement skills, presentation of educational booklets to patients and introduction of online pages in virtual social networks to learn more. Content will be presented in simple and understandable language for the patient. The educational booklet and online pages of social networks will be prepared by the researcher based on the educational content and with the final approval of the faculty members of Shahid Beheshti University of Medical Sciences. The online pages of social networks will contain uploaded texts, images and educational videos; The membership link will only be available to patients of the intervention group or one of their family members (if the patient wishes). The time of use of educational materials will be at the disposal of the patient, who can adjust it according to his needs. The ostomy bag replacement simulation tool will include one-piece and two-piece ostomy bag, ostomy size measurement template, scissors, marker, gloves, ostomy powder, ostomy paste, ostomy skin protection ring, ostomy belt, intestinal ostomy simulator. The patient will have Practical work on the simulator under the guidance of a wound and ostomy nurse to familiarize with how to change the ostomy bag and related tips to prevent skin complications related to ostomy. The patient's family and their caregivers will be allowed to attend the training session.
Category
Other

2

Description
Control group: (Usual training) For the patients in the control group, there will be no training by the research team. These patients will be trained in the usual way, i.e. after surgery and before discharge.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital (Tehran)
Full name of responsible person
Dr. Hasani
Street address
A-a-rabi Ave.
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Email
taleghanihospital@sbmu.ac.ir

2

Recruitment center
Name of recruitment center
Imam Hosein Hospital (Tehran)
Full name of responsible person
Dr. Sadeghi
Street address
Shaheed Madani Ave.
City
Tehran
Province
Tehran
Postal code

1617763141
Phone
+98 21 7755 8001
Email
info@ehmc.ir

3

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospial (Tehran)
Full name of responsible person
Dr. Abdollahi Majd
Street address
Shahrdari Ave.
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
pr_shohada@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Vice President of Research and Technology
Street address
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, No. 2660, Vali Asr Ave., Niayesh Cross Road, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
sbnmf@sbmu.ac.ir
Web page address
https://nm.sbmu.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahnaz Ilkhani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursing
Street address
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, No. 2660, Vali Asr Ave., Niayesh Cross Road, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
m_ilkhani@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahnaz Ilkhani
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursing
Street address
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, No. 2660, Vali Asr Ave., Niayesh Cross Road, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717433
Phone
+98 21 8865 5366

Email
m_ilkhani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Mahnaz Ilkhani

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursing

Street address
School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, No. 2660, Vali Asr Ave., Niayesh Cross Road, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 8865 5366

Email
m_ilkhani@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data collected from assessed variables can be shared after de-identification.

When the data will become available and for how long
As soon as the article is published, it can be shared.

To whom data/document is available
All researchers and interested parties are allowed to receive research data.

Under which criteria data/document could be used
Sending a request via email is required to receive data by researchers and interested parties.

From where data/document is obtainable
Sending a request via email is required to receive data by researchers and interested parties. email: m_ilkhani@yahoo.com

What processes are involved for a request to access data/document
Sending a request via email is required to receive data by researchers and interested parties.

Comments