Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of self-care education with two methods of Teach-back and pictorial on self-efficacy and wound healing of stoma in patients with colostomy

Protocol summary

Study aim

Comparison of self-care education with two methods of Teach-back and pictorial on self-efficacy and wound healing of stoma in patients with colostomy

Design

A randomized clinical trial with a control group, with three parallel groups

Settings and conduct

The present study will be performed in three groups of 111 patients with colostomy (two intervention groups and one control group) at Basat hospital of Hamadan in 2019. In the two intervention groups, training will be taught in two methods of teach-back and pictorial. Training sessions will be held on the cause of colostomy, ostomy care methods and types of colostomy bags.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having literacy of reading and writing, Undergoing colostomy surgery for the first time, Ages between 18 to 65 years Exclusion criteria: Failure to attend more than one training session, Discharge before the end of the intervention

Intervention groups

The tutorial will be run using the teach-back and pictorial method. In teach-back method, educational content will be taught to the patient by a face-to-face researcher in plain language without the use of medical terminology then the patient is asked to express the educational content in their own language. Pictorial training will be done with simple pictures, posters, and drug labels to remind of taking medications. In control group face-to-face training will be done at the time of admission (as routine training) in the ward.

Main outcome variables

Self-efficacy and wound healing of ostomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160110025929N27**
Registration date: **2019-09-08, 1398/06/17**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-08, 1398/06/17**
Update count: **0**

Registration date

2019-09-08, 1398/06/17

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of self-care education with two methods of Teach-back and pictorial on self-efficacy and wound healing of stoma in patients with colostomy

Public title
Comparison of self-care education with two methods of Teach-back and pictorial on self-efficacy and wound healing of stoma

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Ages between 18 to 65 years Undergoing colostomy surgery for the first time Having literacy of reading and writing

Exclusion criteria:
Not willing to participate in the study Transfer the patient to another health center

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: **111**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple random allocation will be done using a random number table. Patients will be randomly divided into three groups intervention(A, B) and control (c).

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 Hamadan University of Medical Sciences

Street address
Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

City
Hamadan

Province
Hamadan

Postal code
38698-65178

Approval date
2019-07-20, 1398/04/29

Ethics committee reference number
IR.UMSHA.REC.1398.328

Health conditions studied

1

Description of health condition studied
Colostomy

ICD-10 code
Z43.3

ICD-10 code description
Encounter for attention to colostomy

Primary outcomes

1

Description
Self- efficacy and stoma wound healing

Timepoint
Before and one month after intervention

Method of measurement
Ostoma self-efficacy questionnaire and assess the skin around the stoma with a checklist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group(1): The tutorial will be run using the teach-back method. Educational content will be taught to the patient by a face-to-face researcher in plain language without the use of medical terminology. The patient is then asked to express the educational content in his / her own language. If the patient does not understand correctly, the content will be re-educated.

Category
N/A

2

Description
Intervention group(2): Training will be done with simple pictures, posters, and drug labels to remind of taking medications .

Category
N/A

3

Description

Control group: In the control group face-to-face training will be done at the time of admission(as routin education) in the ward.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Mahnaz Khatiban

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

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Email

khatiban@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Shahid Fahmideh St., Hamadan University of Medical Sciences, Hamadan

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Deputy of research and technology

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

Hamedan University of Medical Sciences

Full name of responsible person

Mahnaz Khatiban

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mahnaz Khatiban

Position

Associate professor

Latest degree

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Person responsible for updating data

nasrinrajabi.md@gmail.com

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Zoleikha Rajabi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available