Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of self care education on self-efficacy and life style of patients with an intestinal ostoma

Protocol summary

Study aim
Determining the effect of self-care education on self-efficacy and lifestyle of people with gastrointestinal ostomy

Design
A clinical trial with a control group with parallel groups, randomized on 74 patients. Random number table was used for randomization.

Settings and conduct
After completing the pre-test, all individuals who met the inclusion criteria were divided into two groups of intervention and control after completing the informed consent form using a random number table. The pre-test, which includes a personal information questionnaire, self-efficacy questionnaire and lifestyle questionnaire, was completed in both groups. Then, based on the self-care needs of these individuals, face-to-face training sessions were conducted in the intervention group using booklets and lectures in four 45-minute sessions. The control group received routine training of hospital staff. After 50 days, the subjects completed the questionnaires again.

Participants/Inclusion and exclusion criteria
Anyone who has a gastrointestinal ostomy and one month has passed since their ostomy was implanted, and is able to read, write and communicate, and does not have a mental disorder, can be included in the study.

Intervention groups
After the subjects were divided into intervention and control groups, the pretest, which includes a personal information questionnaire, self-efficacy questionnaire and lifestyle questionnaire, was completed in both groups. Then, based on the self-care needs of these people, face-to-face training sessions were conducted in the intervention group using booklets and lectures in four 45-minute sessions. The control group received routine training of hospital staff. After 50 days, the subjects completed the questionnaires again.

Main outcome variables
Self-care, Self-efficacy, life style

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200708048061N1**
Registration date: **2020-12-06, 1399/09/16**
Registration timing: **retrospective**

Last update: **2020-12-06, 1399/09/16**
Update count: **0**

Registration date
2020-12-06, 1399/09/16

Registrant information

Name
Fatemeh Yousefli

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-02-20, 1398/12/01

Actual recruitment start date
2019-09-23, 1398/07/01

Actual recruitment end date
2020-04-20, 1399/02/01

Trial completion date

2020-05-25, 1399/03/05

Scientific title
The Effect of self care education on self-efficacy and life style of patients with an intestinal ostoma

Public title
Investigating theeffect of training on self-efficacy and lifestyle of ostomates

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
At least one month after ostomy implanation Age between 18-65 Literacy for reading and writing Lack of psychiatric disorders Failure to attend self-care training sessions in the last six month Ability to communicate Ability to collaborate

Exclusion criteria:
Withdrawal from continuing research Absence in two sessions of training sessions Participate in self-care training sessions while participating in research

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: **74**
Actual sample size reached: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be continuous at the sample section stage and then a simple random method will be used to distribute the samples to the intervention and control groups. The samples will be distributed to two groups of intervention and control by a third party who is unaware of the study flow using the table of random numbers.

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 in Biomedical Research

Street address
Ebne Sina Hospital, The beginning of Ayatollah Kashani Highway

City
Tehran

Province
Tehran

Postal code
71348-14336

Approval date
2019-05-22, 1398/03/01

Ethics committee reference number
IR.IUMS.REC.1398.167

Health conditions studied

1

Description of health condition studied
Patient with gastrointestinal ostomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Ostomy self-efficacy score higher than 42

Timepoint
Measurement of self-efficacy level before intervention and 50 days after

Method of measurement
How to measure the self-efficacy variable is the ostomy self-efficacy questionnaire.

2

Description
Lifestyle score above 140

Timepoint
Measuring lifestyle level before the medal and 50 days later

Method of measurement
General Lifestyle Questionnaire

Secondary outcomes

1

Description
This study has no secondary outcome variables.

Timepoint
This study has no secondary outcome variables.

Method of measurement
This study has no secondary outcome variables.

Intervention groups

1

Description
Intervention group: The samples will be distributed to the intervention and control groups by a third person who is unaware of the study using a random number table. The pre-test in the intervention group will include lifestyle tools and ostomy self-efficacy tools. Then, based on the educational needs of the patients under study and in accordance with these needs, a face-to-face training program using an educational booklet and lectures in the field (ostomy care, skin care around the ostomy, bag replacement, diet, activity and exercise, sexual activity, Travel, bathing and swimming).The training program will be done in 4 sessions of 45 minutes. After the training sessions, the educational content will be followed up by the researcher by phone every 15 days. After 50 days, the samples will be re-completed at the medical centers and the completed tools will be re-tested as a pre-test.

Category
Other

2

Description
Control group: The control group will receive routine training by medical staff at the same time as the pre-test group. In the control group, routine hospital follow-ups will be performed. After 50 days in the control group, a post-test is taken and finally the educational booklet is delivered to this group.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool Akram Educational and Medical Center

Full name of responsible person
Fatemeh Yousefli

Street address
Rasoul Akram Hospital., corner of Mansouri St., Niayesh St.,Sattar Khan St

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2

Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr. Seyed Abbas Motavlian

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Iran University of Medical Sciences., next to Milad Tower., Hemmat Highway

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Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person

Fatemeh Yousefli

Position
Master student of Internal Surgery Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Full name of responsible person
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Latest degree
Master

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Medical Education

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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
Nursery

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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
Not applicable

Analytic Code
Not applicable

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

Title and more details about the data/document
Some of the unidentifiable information is the data that can be shared after the end of the study.

When the data will become available and for how long
Access starts 6 months after the results are published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
The documentation can only be used for review in research.

From where data/document is obtainable
Fatemeh Yousefli Phone number 09369903979 Email adress: fatemeh.yousefli711116@gmail.com

What processes are involved for a request to access data/document
After the applicant's request via email, the request will be submitted to the tutor and if she agrees, the request data will be sent via email.

Comments