

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

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

Protocol summary

Self-care, Self-efficacy, life style

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

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

Country

Iran (Islamic Republic of)

Phone

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Email address

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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

Rasool Akram Hospital., corner of Mansouri St.,
Niayesh St., Sattar Khan St

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2

Recruitment center

Name of recruitment center

Firoozgar Educational and Medical Center

Full name of responsible person

Fatemeh Yousefli

Street address

Firoozgar Hospital., Beh Afarin St., Karim Khan Zand
St., Valiasr Square

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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

Street address

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

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Tehran

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1449614535

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admins@iums.ac.ir

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

Street address

Ebne Sina Hospital, at the beginning of Ayatollah
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Master student of Internal Surgery Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Fariba Nasiri Ziba

Position

Faculty of Nursing, Internal Surgery Field

Latest degree

Master

Other areas of specialty/work

Medical Education

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Yousefli

Position

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
address: 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