

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The assessment of self-care education program effect on Quality of Life and Stress in intestinal ostomy patients

Protocol summary

Summary

The aim of this study is determine of self-care education program effect on Quality of Life and Stress in intestinal ostomy patients . The study population of 76 patients with intestinal ostomy referred to clinics of colorectal in Hazrat e Rasool and firoozgar hospitals that have inclusion criteria . Method sampling will be continuously . On the stage before the completion of the questionnaire will attending the intervention was for that time completion will be 15-20 minutes and then compile self education program for educational booklet and pamphlet about intestinal ostomy diseases , ostomy late complications and etc . Will performed in three one-hour sessions during the three weeks for the test group . The team training will be consists of a group of 8 to 10 people. During the study all subjects will receive standard care . Quality of life and stress test and control groups , in before the process of self-care education and 2 months after the training, by Perceived Stress Scale (PSS-14) and the City of Hope Quality of Life Ostomy patients questionnaire (COH-QOL) will be measured and in the end the amount of stress and quality of life of the two groups will be evaluated .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070428781N1**

Registration date: **2016-10-21, 1395/07/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-21, 1395/07/30

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research funding of Iran University of medical sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of self-care education program effect on Quality of Life and Stress in intestinal ostomy patients

Public title

The effect of education on quality of life and stress in patients with intestinal stoma

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria were: having a permanent or temporary intestinal stomy , be at least 18 years old , be have mental disorder , speech , vision and hearing and the delicate hand movements based health records and physician's instructions (such as arthritis rheumatoid and

physical illnesses of the upper limb), Passed at least one month from the time of surgery , the ability to speak the Persian language , read and write. Exclusion criteria : Lack of patient satisfaction from participating in continuing research , death of the patient , absent in one education session , the occurrence of any complication or severe disability while performing the study .

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

Ethic committee of Iran University Of Medical Sience

Street address

Iran University of Medical Sciences ,Hemat Highway

City

tehran

Postal code

Approval date

2016-04-05, 1395/01/17

Ethics committee reference number

IR.IUMS.REC.1394.9211196235

Health conditions studied

1

Description of health condition studied

gastrointestinal cancer

ICD-10 code

C26.9

ICD-10 code description

Ill-defined sites within the digestive system

Primary outcomes

1

Description

Quality of life for people with ostomy

Timepoint

At beginning and two months after completion of the intervention

Method of measurement

City of Hope-Quality of Life-Ostomy Questionnaire(COH-QOL)

Secondary outcomes

1

Description

Stress

Timepoint

At beginning and two months after completion of the intervention

Method of measurement

Perceived Stress Scale (PSS-14)

Intervention groups

1

Description

The test group will be divided into groups of 8 to 10 people . After the compilation of self-care education program in accordance with the opinion of the supervisor for educational booklet and pamphlet about intestinal ostomy diseases , ostomy late complications , nutrition , exercise , training , and advice about the care of the skin around the stoma will performed in three one-hour sessions during the three weeks for the test group . Training sessions to lecture , group discussion with the use of slides and training booklet will be administered . Educational sessions , training as much as possible in the form of a simple , perceptible without the use of specialized terminology and medicine will be presented . After the completion of educational intervention to the post test phase will be asked of the people group intervention that education program at the time of their presence in home to be operated .

Category

Lifestyle

2

Description

The control patients will receive standard hospital care

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat e Rasool Hospital

Full name of responsible person

Mojtaba Zibadi

Street address**City**

Tehran

2

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Mojtaba Zibadi

Street address**City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Ali Javad Mousavi

Street address

Room #503, 5th floor, Central building of Iran University of Medical Sciences, between Chamran and Hemmat Expways, Hemmat Expway

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mojtaba Zibadi

Position

Nursing Msc Student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty