Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of telenursing based training on the self-efficacy of patients with stoma.

Protocol summary

Study aim

Determining the effect of telenursing based training on the self-efficacy of patients with stoma in Zahedan city in 2022

Design

First, we select 80 patients with stoma who meet the study entry criteria as available sampling, then, using blue and green color cards that are in the white envelopes, we randomly divide the patients into two groups of 40 people, intervention and control.

Settings and conduct

Patient information is obtained from the archives of hospitals covered by Zahedan University of Medical Sciences. Patients will be selected who have had at least one month since their ostomy surgery; Because they have faced problems and limitations.

Participants/Inclusion and exclusion criteria

The patient has not participated in stoma care training courses A member of the patient's family should not be part of the treatment staff The patient is not from the treatment staff The patient should not be supported by the Iran Ostomy Association At least one month has passed since the patient's ostomy surgery The age of people should be between 14 and 70 years The patient or their family caregiver has the ability to work with software and smart phones The patient does not have any impairment in speech, hearing or vision The patient has a smart phone The patient must live in Zahedan city

Intervention groups

patients are randomly divided into two control and intervention groups after available sampling. The control group only sees routine trainings; the intervention group, in addition to routine trainings, receives the special training of the researcher, which is prepared in the from of an application installed on the smart mobaile phone of the patients and they are trained. Patients' self_efficacy is measured by the stoma self_efficacy scale questionnaire before the intervention, one and three months after the intervention.

Main outcome variables

Self_efficacy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230303057596N1**
Registration date: **2023-07-31, 1402/05/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-31, 1402/05/09**
Update count: **0**

Registration date

2023-07-31, 1402/05/09

Registrant information

Name
Mostafa Parsa
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 5542 1977
Email address
parsam3@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of telenursing based training on the self-efficacy of patients with stoma.

Public title
The effect of telenursing based training on the self-efficacy of patients with stoma.

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The patient has not participated in stoma care training courses A member of the patient's family should not be part of the treatment staff The patient is not from the treatment staff The patient should not be supported by the Iran Ostomy Association At least one month has passed since the patient's ostomy surgery The age of people should be between 14 and 70 years The patient or their family caregiver has the ability to work with software and smart phones The patient does not have any impairment in speech, hearing or vision The patient has a smart phone The patient must live in Zahedan city Also, patients who have a stoma due to cancer with grade 1 and 2 can enter the study

Exclusion criteria:
Cancer patients with grade 3 and 4

Age
From **14 years** old to **70 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
Patients will be randomly divided into two groups of intervention and control by selecting colored cards that fall into a white envelope. Green and blue colored cards are prepared and randomly placed inside a white envelope and patients will randomly choose a card. Green is a sign of the patient's entry into the control group and the blue is a sign of the patient's entry into the intervention group.

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
Zahedan University of Medical Sciences (Research Ethics Committee)

Street address
Persian Gulf Highway, Salamat Blvd.

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
9816913396

Approval date
2022-11-20, 1401/08/29

Ethics committee reference number
IR.ZAUMS.REC.1401.420

Health conditions studied

1

Description of health condition studied
stoma

ICD-10 code
Z93.3

ICD-10 code description
Colostomy status

Primary outcomes

1

Description
self-efficacy score

Timepoint
Before starting the study, one month and three months after the intervention

Method of measurement
Stoma self-efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First, the self-efficacy questionnaire is given to patients to complete. Then in this group, in addition to the routine trainings that the patients receive, the researcher installs special trainings using an application on the patients' smart phones and teaches them. Patients have 3 weeks to be trained using the mobile application. One and three months after the intervention, the self-efficacy questionnaire will be given to the patients to be completed.

Category
Lifestyle

2

Description
Control group: First, the self-efficacy questionnaire is given to patients to complete. The educational program is not installed on the mobile phones of these patients. These patients are not given any special training. After one and three months, the self-efficacy guestionnaire is given to the patients to be completed.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ibn Abi Talib Hospital
Full name of responsible person
DR.Amir Gergij
Street address
Ali Ibn Abi Talib Hospital
City
Zahedan
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Sistan-va-Balouchestan
Postal code
9816743111
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+98 54 3329 5570
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nur.mostafa.parsa@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences, Research assistant
Full name of responsible person
Nur Mohammad Bakhshani
Street address
Dr. Hasabi Square - Zahedan University of Medical Sciences campus
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9816743111
Phone
+98 54 3329 5570
Email
Nur.mostafa.parsa@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan University of Medical Sciences, Research assistant
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
Zahedan University of Medical Sciences
Full name of responsible person
Mostafa Parsa
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
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
Questionnaire form and data analysis collected.
When the data will become available and for how long
Starting the access period year1402
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Statistical result.
From where data/document is obtainable
Zahedan University of Medical Sciences Library Country Theses System Researcher Gmail: Nur.mostafa.parsa@gmail.com phone 09033321800
What processes are involved for a request to access data/document
With a written request to the Research Vice_Chancellor of Zahedan University of Medical
Comments
Does not have