

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of tele-nursing on self-efficacy and sense of coherence of patients with ostomy

Protocol summary

Study aim

To determine the effect of Tele-nursing on self-efficacy and sense of coherence of patients with ostomy attending Tehran Ostomy Association

Design

This study is a controlled randomized clinical trial in which the research sample were selected based on inclusion criteria and will be assigned to control (n=60) and intervention (n =60) groups through throwing coin.

Settings and conduct

Study place will be Tehran Ostomy Association. Patients in both intervention and control groups will enrolled immediately after receiving the usual education of the association and the demographic, self-efficacy and sense of coherence questionnaires will be filled through interview with patients. Then the intervention group will receive 6 phone calls (in the form of three calls in the first week, two calls in the second week and one call in the third and fourth weeks, and also sending an SMS before each call) during the follow-up period. A month after entering the study, the questionnaires will be filled again in both groups and the results will be analyzed using the spss statistical software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least one kind of ostomy; having at least 18 years of age, having the ability to read, write and answer the questions.

Intervention groups

Intervention group: In addition to the usual education of the Ostomy Association, tracking and training through telenursing will be done during a month in the form of three calls in the first week, two calls in the second week and one call in the third and fourth weeks, and also sending an SMS before each call. Control group: they only will receive usual education of the Ostomy Association.

Main outcome variables

Improvement of the sense of coherence and self-efficacy in intervention group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161011030261N2**

Registration date: **2018-10-16, 1397/07/24**

Registration timing: **retrospective**

Last update: **2018-10-16, 1397/07/24**

Update count: **0**

Registration date

2018-10-16, 1397/07/24

Registrant information

Name

Parisa Saeidi Ortakand

Name of organization / entity

Shahid Beheshti University of Medical Sciences & Health Services

Country

Iran (Islamic Republic of)

Phone

+98 21 8865 5366

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parisa-saeidi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shahidbehshiti University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2017-04-19, 1396/01/30

Trial completion date

empty

Scientific title

The effects of tele-nursing on self-efficacy and sense of coherence of patients with ostomy

Public title

The Effect of Tele_ Nursing on Self _ Efficacy and Sense of Coherence

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 80 years Maximum duration of having ostomy should be 60 days having reading and writing abilities

Exclusion criteria:**Age**

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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**

The Ethics Committee, International Branch, Shahid Beheshti University Of Medical Sciences,

Street address

No19, beside Hemmat Bridge, Abbaspour Street, Valiasr Street

City

Tehran

Province

Tehran

Postal code

1434875451

Approval date

2016-07-18, 1395/04/28

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.248

Health conditions studied**1****Description of health condition studied**

Ostomy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Self Efficacy

Timepoint

At the first time of coming to the association and one month later

Method of measurement

Self Efficacy Scale

Secondary outcomes**1****Description**

Sense of Coherence

Timepoint

At the first time of coming to the association and one month later

Method of measurement

Sense of Coherence assessment tool

Intervention groups**1****Description**

Intervention group: In addition to the usual education of the Ostomy Association, tracking and training through telenursing will be done during a month in the form of three calls in the first week, two calls in the second week and one call in the third and fourth weeks.

Category

Other

2**Description**

Control group: usual education of the Ostomy Association will be done.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Ostomy Association

Full name of responsible person

Dr Anaraki

Street address

No 6, Esmaeilzade Alishah Alley, Mirzaei Bighash Alley, Fatemi street.

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Province

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1414

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Email

info@iranostomy.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mahrokh Dolatian

Street address

at the beginning of Nyayesh highway, Valiasr Street

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sbnmf@sbmu.ac.ir

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 of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

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

Persons

Person responsible for general inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parisa Saeidi Ortakand

Position

Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data will not be published and will be reserved and won't be disseminated. If necessary other researchers will be referred to the authors.

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

Not applicable