

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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

##### Email address

parisa-saeidi@sbm.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, Abbaspoor 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, Esmailzade Alishah Alley, Mirzaei Bighash Alley, Fatemi street.

**City**

Tehran

**Province**

Tehran

**Postal code**

1414

**Phone**

+98 21 8896 9602

**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

**City**

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**Province**

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**Postal code**

1985717443

**Email**

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

**Street address**

Shahid Beheshti University of Medical Sciences, at the beginning of Nyayesh highway, Valiasr Street

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**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Camelia Rohani

**Position**

PHD

**Latest degree**

Ph.D.

**Other areas of specialty/work****Street address**

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### Person responsible for updating data

**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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**Fax**

**Email**

Parisa-saeidi@sbmu.ac.ir

**Web page address**

## 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