

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Aug 2026

### Comparitive study on the effects of simulation and demonstration-return demonstration methods in ostomy care training on self-efficacy and adjustment in patients with an intestinal stoma

#### Protocol summary

##### Summary

This study is a single-blind randomized trial with two groups of pre- and post-test. The aim of study is Comparison the effects of simulation and demonstration-return demonstration methods in ostomy care training on self-efficacy and adjustment in patients with an intestinal stoma. The study population included patients with intestinal ostomy (colostomy or ileostomy). Inclusion criteria Includes having healthy vision and hearing and having no disability, psychological disorders and dependence for their cares. Exclusion criteria include complication and Unwillingness to continue to participate in the study. The total sample size is 23 patients per group so 46 patients in both group were considered. In this study, the intervention will be carried out in separate groups, one group educate with simulation method and another group educate with demonstration- return demonstration. For each group 4 training at the clinic will be held at approximately 0.5 hours (3 sessions as individual theory and practice training and the last session as a meeting group about ostomy care). Simulation group Practice ostomy cares on designed simulator based on simulation methods and demonstration- return demonstration group display Cares on their own ostomy based on demonstration-return demonstration method. Outcomes of study are self-efficacy and ostomy adjustment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014113020162N1**  
Registration date: **2015-04-04, 1394/01/15**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-04-04, 1394/01/15

##### Registrant information

###### Name

Zohre Pouresmail

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3662 9069

###### Email address

pouresmailz921@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2015-04-05, 1394/01/16

##### Expected recruitment end date

2015-08-22, 1394/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparitive study on the effects of simulation and demonstration-return demonstration methods in ostomy care training on self-efficacy and adjustment in patients with an intestinal stoma

##### Public title

Ostomy care education to patients with intestinal ostomy

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria for patients recently have ostomy surgery: Between 18 and 65 years old; Patient that Singed Consent Knowingly; Having healthy vision and hearing and having no disability; Have no psychological disease, movement disability and balance disorders; Have no experience of having intestinal ostomy in family members; Do not receive any regular and documented ostomy training. Inclusion criteria for patients who already have ostomy surgery: Between 18 and 65 years old; Patient that Singed Consent Knowingly. Exclusion criteria: Willingness to continue participation in the study; Complications that commonly affect the Regular care and need to hospitalization; Patient death

## Age

From **17 years** old to **65 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **46**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Mashhad University of Medical Sciences

##### Street address

Vice Chancellor for research, Ghorashy Building,  
University St, Mashhad

##### City

Mashhad

##### Postal code

9177899191

#### Approval date

2015-03-14, 1393/12/23

#### Ethics committee reference number

930866

## Health conditions studied

### 1

#### Description of health condition studied

Ineffective training

#### ICD-10 code

Z55.8

#### ICD-10 code description

other problems related to education and literacy

## Primary outcomes

### 1

#### Description

Self efficacy

#### Timepoint

Before the intervention, after the intervention, 1.5 month  
after intervention

#### Method of measurement

self efficacy questionnaire

## Secondary outcomes

### 1

#### Description

adjustment

#### Timepoint

Before the intervention, After the intervention, 1.5 month  
after intervention.

#### Method of measurement

Ostomy adjusment inventory 23 questionnaire

## Intervention groups

### 1

#### Description

Intervention1: The demonstration- return demonstration ostomy care training is done in 4 sessions, in the first session teach about the types of ostomy, diet, bathing, authorized and unauthorized activities and warning signs, gas and odor control in colostomy, signs and symptoms of dehydration and The importance of leakage prevention. In the second session, patient educated about how to change the ostomy pouch and care of skin that around the ostomy with demonstration method and patient practice cutting ostomy bag by return demonstration. This session held 1-3 days after the first session. In third session, patient change ostomy pouch and skin care around the ostomy without nurse aid by return demonstration. Researcher completes teaching flow sheet. The session will be held one week after the second session. In the fourth session common complication of ostomy and how to prevent them educated by PowerPoint software. The group members discuss and respond to each other's questions. The meeting will be held one week after the third session.

#### Category

Other

## 2

### Description

intervention2: The simulation ostomy care training is done in 4 sessions, in the first session teach about the types of ostomy, diet, bathing, authorized and unauthorized activities and warning signs, gas and odor control in colostomy, signs and symptoms of dehydration. The importance of leakage prevention leakage. Then video will be witch contains ostomy bag substitute teaching and patient practice how to cut the adhesive ostomy bag. In the second session patient learning how to change the ostomy pouch and skin care around the ostomy. Patient participates in Skin care with the physical simulators. The session will be held 1-3 days after the first session. In the fourth session common complication of ostomy and how to prevent them educated by PowerPoint software. The meeting will be held one week after the third session.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Quaem hospital

##### Full name of responsible person

Ghasem Rahmanian

##### Street address

Ahmad abad St, Dr Shariati Square, Mashhad.

##### City

Mashhad

### 2

#### Recruitment center

##### Name of recruitment center

Omid hospital

##### Full name of responsible person

Fatemeh Kavousi

##### Street address

Alandasht Square, Kuhsangi St, Mashhad.

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Mohsen Tafaghodi

##### Street address

Vice Chancellor for research, Ghoraisky Building, University St, Mashhad

### City

Mashhad

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Mashhad 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

Mashhad University of Medical Science

#### Full name of responsible person

Zohre Pouresmail

#### Position

Master Student

#### Other areas of specialty/work

#### Street address

Number 69, South Adibe 1 St, Ghasem abad, Mashhad.

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## Person responsible for scientific inquiries

### Contact

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#### Full name of responsible person

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Phd in Nursing

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Science

**Full name of responsible person**

Zohre Pouresmail

**Position**

Master Student

**Other areas of specialty/work**

**Street address**

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Mashhad.

**City**

Mashhad

**Postal code**

**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*