

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, Ghoraisly 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.

City

Mashhad

Postal code

9189633798

Phone

+98 935 539 2288

Fax

Email

pouresmailz921@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Science

Full name of responsible person

Fateme Heshmati Nabavi

Position

Phd in Nursing

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Doctora Crossroads, Mashhad.

City

Mashhad

Postal code

9137913199

Phone

+98 915 500 2213

Fax

+98 985138591511

Email

heshmatinf@mums.ac.ir

Web page address

9189633798

Phone

+98 935 539 2288

Fax

Email

pouresmailz921@mums.ac.ir

Web page address

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

Number 69, South Adibe 1 St, Ghasem abad,
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