# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Comparison of the Effectiveness of Supported Mirror Viewing Effect on Adjustment, Self-efficacy and Self-disgust with Routine Care in Patients with Permanent Intestinal Ostomy

## Protocol summary

**Study aim**
Determining the effect of Supported Mirror Viewing on Adjustment, Self-efficacy, and Self-disgust in patients with permanent intestinal ostomy

**Design**
A randomized, clinical trial without blinding, with a control group design of 100 permanent ostomy patients. In this study, the simple randomization method is used.

**Settings and conduct**
Patients with permanent intestinal ostomy referred to an ostomy clinic in Kerman city were randomly assigned to control and intervention groups. The safety monitoring and data control committee is blinded to group allocation.

**Participants/Inclusion and exclusion criteria**
Inclusion condition: Age 18 years and older, Having permanent intestinal, sigmoid, or ileum ostomy for at least three months; Ostomy placement due to colorectal cancer; Receive basic training from the ostomy specialist nurse based in the ostomy clinic; Willing to look at the ostomy area and their body in the mirror with the help of the nurse. Exclusion condition: having a temporary ostomy

**Intervention groups**
In this research, the intervention of supported mirror-viewing is performed as a 60-minute face-to-face session in a private place in an ostomy center for 50 patients who have the possibility to attend the ostomy center, and the same session is conducted with the presence of the researcher at the patient's home for those who are unable to be in the center. Fifty patients in the control group just received routine care and training provided by an ostomy nurse in the center.

**Main outcome variables**
Colostomy Self-disgust, Stoma Self-efficacy, Ostomy Adjustment

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20231003059602N1**
Registration date: **2023-10-16, 1402/07/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-16, 1402/07/24**
Update count: **0**

**Registration date**
2023-10-16, 1402/07/24

**Registrant information**

**Name**
Fatemeh Mirzaei

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 939 198 6178

**Email address**
fatemehmirzaei79@yahoo.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-10-07, 1402/07/15

**Expected recruitment end date**
2024-01-05, 1402/10/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of the Effectiveness of Supported Mirror Viewing Effect on Adjustment, Self-efficacy and Self-disgust with Routine Care in Patients with Permanent Intestinal Ostomy

**Public title**
To Investigate the Effectiveness of Supported Mirror Viewing Effect on Adjustment, Self-efficacy, and Self-disgust in Patients with Permanent Intestinal Ostomy
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age 18 years and older Having at least one permanent intestinal, sigmoid, or ileum ostomy due to colorectal cancer, etc. for at least three months Receive routine training from the ostomy specialist nurse in the ostomy clinic Willingness to look at the ostomy area and their body in the mirror with the help of the nurse
**Exclusion criteria:**
Having a temporary ostomy
**Age**
From **18 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **100**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Due to the availability of the ostomy patients' information list in the ostomy center, the simple randomization method is used in this study. First, a person who is not involved in the study prepares a list of patients with permanent ostomy. After checking the inclusion and exclusion criteria, she/he determines the number of eligible patients. Then, she/he writes the patient's admission number, which is a 7-digit code, on a non-transparent paper and pours it into a container. Then another person takes the cards out of the box one by one. The codes with odd numbers from the right side will be assigned to the intervention group and the others will be in the control group. More than 50 people are selected in each group so that if the patient does not want to participate or is excluded from the study, the next person will be replaced. In this study, there is no possibility of blinding the patients and the researcher.
**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**
Ethics committee of Kerman University of Medical Sciences
**Street address**
No. 2, Ibn Sina Street, Deputy of research and technology Bldg.
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913555
**Approval date**
2023-09-27, 1402/07/05
**Ethics committee reference number**
IR.KMU.REC.1402.217

## Health conditions studied

### 1

**Description of health condition studied**
Colorectal Cancer
**ICD-10 code**
K94.0
**ICD-10 code description**
Colostomy complications

## Primary outcomes

### 1

**Description**
The score of Jin et al. Colostomy Self-disgust Questionnaire
**Timepoint**
At the point of recruitment day, immediately after the intervention and three months later
**Method of measurement**
Jin et al. Colostomy Self-disgust Questionnaire

### 2

**Description**
The score of Bekkers et al. Stoma Self-efficacy Questionnaire
**Timepoint**
At the point of recruitment day, immeditely after the intervention and three months later
**Method of measurement**
Bekkers et al. Stoma Self-efficacy Questionnaire

**3**

**Description**
The score of Simmons et al. Ostomy Adjustment Questionnaire
**Timepoint**
At the point of recruitment day, immediately after the intervention and three months later
**Method of measurement**
Simmons et al. Ostomy Adjustment Questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: In this research, the intervention of supported mirror-viewing is performed by the main investigator as a 60-minute face-to-face session in a private place for 50 patients who have the possibility to attend the ostomy center, and the same session is conducted with the presence of the researcher at the patient's home for those who are unable to attend to the center. The educational content of the session is given to the patients in the form of a brochure on the day of the training for practice at home.
**Category**
Rehabilitation

**2**

**Description**
Control group: 50 people who complete the questionnaires at all three specified times are included in the control group, which will receive routine care and training provided by the ostomy nurse. If there will be a positive effect of training on outcome measures, the intervention will be conducted for the control group too.
**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Ostomy Clinic of Shahid Bahonar Hospital of Kerman University of Medical Sciences
**Full name of responsible person**
Fatemeh Mirzaei
**Street address**
Shahid Bahonar Hospital, Gharani Street
**City**
Kerman
**Province**
Kerman
**Postal code**
7613747181
**Phone**
+98 34 3223 5011
**Fax**
+98 34 3132 5830
**Email**
fatemehmirzaei79@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Abedin Iranpour
**Street address**
کرمان، خیابان ابن سینا، معاونت تحقیقات و فناوری، پلاک 2
**City**
Kerman
**Province**
Kerman
**Postal code**
7619813159
**Phone**
+98 34 3226 3855
**Fax**
+98 34 3226 3857
**Email**
a.iranpour@kmu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Kerman University of Medical Sciences
**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**
Kerman University of Medical Sciences
**Full name of responsible person**
Omsalimeh Roudi Rashtabadi
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery

**Street address**
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913555
**Phone**
+98 34 3132 5201
**Email**
fatroody@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Omsalimeh Roudi Rashtabadi
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery
**Street address**
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
**City**
Kerman
**Province**
Kerman
**Postal code**
7616913555
**Phone**
+98 34 3132 5201
**Email**
fatroody@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Kerman University of Medical Sciences
**Full name of responsible person**
Omsalimeh Roudi Rashtabadi
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery
**Street address**
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
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+98 34 3132 5201
**Email**
fatroody@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Not applicable