Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 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
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Iran (Islamic Republic of)
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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Abedin Iranpour
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کرمان، خیابان ابن سینا، معاونت تحقیقات و فناوری، پلاک 2
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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
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Position
Assistant Professor
Latest degree
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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