

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative study of the effect of face to face and multimedia education on the adaptation and anxiety of People with intestinal stoma

Protocol summary

Study aim

Comparison of the effect of face to face and multimedia education on the adaptation and anxiety of people with intestinal stoma

Design

Three groups randomized clinical trial

Settings and conduct

The present study is a randomized clinical trial study. Total of 126 individuals with intestinal stoma by available sampling will be chosen. The research population is people who will be admitted to two selected hospitals of Iran and Tehran Medical Sciences Universities. The data collection tools included a demographic questionnaire and a questionnaire on adjustment and anxiety of people with intestinal stoma. Control group will be taken routine care. Face-to-face group members will be educated individually in the hospital environment during three consecutive sessions in three consecutive days. To the people of the multimedia group, using the laptop will be taught how to use multi-media software individually. They will also be given a software and guide to using the software, and will answer the patient's questions at the end of the session. Three months after discharge questionnaires will be completed by the patients in all three groups, and at the same time.

Participants/Inclusion and exclusion criteria

Having intestinal stoma (permanent or temporary) Being aged between 70 and 18 years old Having reading and writing skills Ability to work with the computer by the patient or with the help of the family Having mental, speech, vision and hearing health (according to the patient) The absence of physical and mental disabilities such as diabetes, cirrhosis, cardiovascular disease, depression, and

Intervention groups

Control group: taking routine care Face-to-face education group: taking individualized and face-to-face education related to illness Multimedia education group: taking education related to illness using multimedia software

Main outcome variables

Adaptation Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091124002769N7**

Registration date: **2018-09-18, 1397/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

Registration date

2018-09-18, 1397/06/27

Registrant information

Name

Mansoureh Ashghaly Farahani

Name of organization / entity

Iran University Medical Sciences ,Nursing & Midwifery Faculty

Country

Iran (Islamic Republic of)

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+98 21 4365 1615

Email address

farahani.ma@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of face to face and multimedia education on the adaptation and anxiety of People with intestinal stoma

Public title

comparison of Face-to-face and multimedia education on the adaptation and anxiety of People with intestinal stoma

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

(Having intestinal stoma (permanent or temporary Having ages between 70 - 18 years Having reading and writing skills Ability to work with the computer by the patient or with the help of the family Having mental, speech, vision and hearing health (according to)the patient

Exclusion criteria:

The presence of physical and psychological disabilities such as: diabetes, cirrhosis, cardiovascular disease, depression, and

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of assigning samples to the groups is random block type triplex without permutation (21 blocks of 6 of 126 modes) from each center. In this sampling method, different modes of the three groups using the random numbers table are written on six cards, each put into an closed package. These packages are placed in a box and the researcher does not know which samples of research will be selected before choosing the car. The statistician (unaware of the study and the groups) with the choosing one of the packages from the box, determines which of the three patients entered to the study will fall into the which category, respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran Medical Sciences University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1996713833

Approval date

2018-05-15, 1397/02/25

Ethics committee reference number

IR.IUMS.REC 1396.32780

Health conditions studied**1****Description of health condition studied**

Intestinal Stoma

ICD-10 code

Z93.3

ICD-10 code description

Colostomy status

Primary outcomes**1****Description**

Adjustment - Adjustment Score from Ostomy Adjustment Inventory

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Ostomy Adjustment Inventory

Secondary outcomes**1****Description**

Anxiety - Anxiety score from Spielberger questionnaire

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Spielberger questionnaire

Intervention groups

1

Description

Intervention group: Face-to-face education: Individually will be educated in the hospital environment and during three consecutive session in three consecutive days.

Category

Rehabilitation

2

Description

Intervention group: Multimedia education group: At the time of discharging, the CD will be given to patients in this group to use at home. Using laptops, the use of multimedia software will be taught individually.

Category

Rehabilitation

3

Description

Control group: Control group: Taking routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Farshad Heidari

Street address

Emam Khomeini Hospital, Keshavarz blv, Tehran

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Province

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2

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Farshad Heidari

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Rasoul Akram Hospital, Niyayesh St, Sattarkhan, Tehran

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heidarifarshad70@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakooti

Street address

Room #503, 5th floor, Central building of Iran University of Medical Sciences, between Chamran and Hemmat Expways, Hemmat Expway

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heidarifarshad70@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mansoureh Farahani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, No 6 , Rashid
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mansoureh Farahani

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data will be shared after unidentifiable people

When the data will become available and for how long

Start the access period 3 months after printing the
results

To whom data/document is available

Anyone ask for it, the data will be sent to them

Under which criteria data/document could be used

Any use of the documentation is allowed

From where data/document is obtainable

Dr Mansoureh Farahani- School of Nursing and Midwifery
, No 6 , Rashid Yasemi st , Vali-e-asr Ave , Tehran, Iran
0098 21 43651000

What processes are involved for a request to access data/document

The request is submitted in writing or verbally, and then
the data will be sent in 1 month

Comments