Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

Comparative Study of the Effect of Peer Support Program on the Sexual Quality of Life of Stoma Patients

Protocol summary

Study aim
Determination and comparison of the effect of peer support program on the sexual quality of life in ostomy patients referring to Selected Centers of Isfahan

Design
The Randomized clinical trial with control group,supportive, with parallel groups without blinding, Random allocation of samples using Permutation blocks with 58 people as the sample.

Settings and conduct
After collecting the code of ethic committee and coordinating with the authorities of the research centers, the researcher selects the eligible samples by simple random sampling.Then she divides them into intervention and control groups randomly using permutation blocks.The intervention group will have 4 sessions with their peers during the course of a month to share their experiences under the supervision of the researcher.The control group will also receive the relevant training after the completion of the study. Both groups fill the Sexual Quality of Life Questionnaires before, immediately and one month after the intervention in a private environment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having a permanent ostomy; passing at least 3 months from surgery and being married
Exclusion criteria: patient's unwillingness to participate in the study.

Intervention groups
Intervention:The members of this group will have 4 sessions with their peers during the course of a month to share their experiences under the supervision of the researcher. Control: Individuals of this group do not enter the peer meetings during the study.

Main outcome variables
Determination of the score of Sexual Quality of life of patients and the underlying factors associated with it; Determination of the effectiveness of peer support program on sexual quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190603043803N1**
Registration date: **2019-08-18, 1398/05/27**
Registration timing: **prospective**

Last update: **2019-08-18, 1398/05/27**
Update count: **0**

Registration date
2019-08-18, 1398/05/27

Registrant information

Name
Ladan Naseh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3777 6981

Email address
naseh@nm.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparative Study of the Effect of Peer Support Program on the Sexual Quality of Life of Stoma Patients

Public title
The Effect of Peer Support Program on the Sexual Quality of Life of Stoma Patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having a permanent Intestinal Stoma (Ileostomy and Colostomy) Pass at least 3 months from the surgery Being married Having complete alertness and consciousness Being fluent in persian
Exclusion criteria:
Patient dissatisfaction to participate in the study Having a history of participation in any related training program or research Having alcohol or drug addiction or taking medications that affect the sexual function Having advanced diseases of vital organs
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, selected samples will randomly assign to the control and intervention groups based on the permutation blocks method. The blocks in volume of 4 are product using random numbers by a computer and for allocation in these blocks; two members of the peer and control groups will be placed for each block.
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 in research Committee of Isfahan University of Medical Sciences.
Street address
Hezar Jareeb Ave.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-07-09, 1398/04/18
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.203

Health conditions studied

1

Description of health condition studied
Intestinal Ostomy (Ileostomy)
ICD-10 code
Y83.3; Z43
ICD-10 code description
Surgical operation with formation of external stoma; Attention to ileostomy

2

Description of health condition studied
Intestinal Ostomy(Colostomy)
ICD-10 code
Y83.3; Z43
ICD-10 code description
Surgical operation with formation of external stoma; Attention to colostomy

Primary outcomes

1

Description
one primary outcome variable is men's Sexual Quality of Life score in the men's Sexual Quality of Life questionnaire.
Timepoint
Before the intervention(pretest), immediately and one month after the intervention(post tests)
Method of measurement
The Men's Sexual Quality of Life Questionnaire is used. This questionnaire has 11 questions and it is scored based on a six-point Likert scale ranging from 1 to 6(quite disagree to quite agree). The range of questionnaire's score is from 11 to 66 and the higher score obtained from the questionnaire indicates the higher sexual quality of life.

2

Description
Another primary outcome variable is women's Sexual Quality of Life score in the women's Sexual Quality of Life questionnaire.
Timepoint
Before the intervention(pretest), immediately and one month after the intervention(post tests)

Method of measurement
The Women's Sexual Quality of Life questionnaire is used. This questionnaire has 18 questions and is scored based on a six-point Likert scale ranging from 1 to 6 (strongly disagree to strongly agree). The range of questionnaire's score is from 18 to 108 and the higher the score obtained from the questionnaire, the higher the quality of sex life.

Secondary outcomes

empty

Intervention groups

1

Description
The intervention of this study is using peer support program, which is organized as 4 group sessions to share common experiences of individuals with each other in order to increase their sexual quality of life.These sessions are weekly and a 90-60 minute session is held every week. It should be noted that in the pretest stage, those who have higher scores from the quality of life questionnaire as well as are interested in leading the group are selected as leaders of the group of peers.
Category
Other

2

Description
Control group: Individuals of this group, like other eligible study samples, is selected by simple random sampling. Then, they are randomly assigned to the control group using permutation blocks and no intervention is made on sexual quality of life for this group. Then, their score of sexual quality of life is compared with the intervention group(peer group) before, immediately and after the study.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Medical Educational Center
Full name of responsible person
Dr. Mehdi Nasr Isfahani
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Soffeh Blvd., Alzahra Hospital
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2

Recruitment center
Name of recruitment center
Kashani Medical Educational Center
Full name of responsible person
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3

Recruitment center
Name of recruitment center
Amin Medical Educational Center
Full name of responsible person
Dr. Mohammad Ali Pourmirzaei
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Sonbolestan Alley., Ibne Sina Ave., Amin Hospital
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4

Recruitment center
Name of recruitment center
Seyyed Alshohada Hospital
Full name of responsible person
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5

Recruitment center
Name of recruitment center
Alaa., Center for Prevention and Control of Cancer
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Deputy of research and technology., Isfahan University of Medical Sciences
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Email
research@mui.ac.ir
Web page address
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Ladan Naseh
Position
Senior Lecturer
Latest degree
Master
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Ladan Naseh
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Senior Lecturer
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Main data, after being unidentifiable and respecting the principle of privacy can be shared in the dissertation file and the extant article.
When the data will become available and for how long
Start access to the thesis file is 6 months after the final defense of the thesis by the student Start access to the full text of the article to be redistributed is immediately after printing
To whom data/document is available
All individuals who are researchers at university institutes and researchers working in other institutions, including the private sector, can take action to receive shared data.
Under which criteria data/document could be used
In order to use the results of this study to plan for more comprehensive studies or use the results of this study to design appropriate supportive educational interventions for patients
From where data/document is obtainable
Department of Adult Health Nursing, School of Nursing and Midwifery, Isfahan University of Medical Sciences,Isfahan, Iran. Ladan Naseh Tel: 0098 913 285 0361 Email: Naseh@nm.mui.ac.ir
What processes are involved for a request to access data/document
Within 7 business days after receipt of the written request by email and the full introduction of the applicant, along with the name of the organization or institution in which they are employed and the data is to be used there, the documents are to be sent.
Comments