Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The effect of the nurse's intentional presence based on holistic approach on coping, stress and anxiety of patients undergoing intestinal obstruction surgeries

Protocol summary

Study aim
The effect of the nurse's intentional presence based on holistic approach on coping, stress and anxiety of patients undergoing intestinal obstruction surgeries.

Design
Clinical trial with control group, parallel groups, double-blind, randomized using block randomization method. Because of lack of similar articles to determine the sample size, a sample size of 10 considered and the main sample is calculated based on pilot study. Blocks of size 4 or 6 blocks will be used for randomization. The generated sequence will be placed in envelopes (each number in one envelope) and envelopes will be numbered.

Settings and conduct
This study will be done in Mashhad educational hospitals on intestinal obstruction patients hospitalized in surgery ward. This study will be double blind in which patients and analysts were kept blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: having informed consent, ability to read and write, being hospitalized<1 month, age between 20 to 70 years old, Bowel resection length<120 cm, having a smartphone patient or family members, ability to use smartphone (patient or the key family member that is called the care giver). Non-inclusion criteria: drug addiction, occurrence of metastasis during the research, suffering from short bowel syndrome

Intervention groups
The intervention is the intentional presence of the holistic nurse.the nurse should start her nursing care based on the patient's trust and his/her exact needs. This research is planned in 5 holistic nursing care meetings in about 30-45 minuets.Simultaneously the researcher give a self care education application to the patient . The intentional presence meetings will be started at the hospital and continued after discharge during one month. Control group: the patients will give all of the routine cares and all of the educational pamphlets would be given to the patients

Main outcome variables
Coping, stress, anxiety

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200811048368N1**
Registration date: **2020-10-11, 1399/07/20**
Registration timing: **prospective**

Last update: **2020-10-11, 1399/07/20**
Update count: **0**

Registration date
2020-10-11, 1399/07/20

Registrant information

Name
Mahboubeh Kavousi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3605 8400

Email address
kavousim971@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-05, 1399/08/15

Expected recruitment end date
2021-08-22, 1400/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of the nurse's intentional presence based on holistic approach on coping, stress and anxiety of patients undergoing intestinal obstruction surgeries

Public title
The effect of the nurse's intentional presence on coping, stress and anxiety of patients undergoing intestinal obstruction
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent Ability to read and write being hospitalized < 1 month Age between 20-70 years old Bowel resection length < 120 cm Having a smartphone patient or one of the family members) Ability to use smartphone (by the patient or the key family member that is called the care giver)
Exclusion criteria:
Drug addiction Occurrence of metastasis during the research Suffering from short bowel syndrome
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **10**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization, blocks of size 4 or 6 will be used to increase the unpredictability of produced random sequence. To hide the generated sequence, envelopes will be numbered and opened for each participant sequentially to determine their group.
Blinding (investigator's opinion)
Double blinded
Blinding description
It is explained to the patient that the patient will participate in a research study, but it is not explained which groups they will be allocated because patient's responses do not be affected by the results of the study and also the statistical analyst only has the statistical data and doesn't know about group of each patient.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
NO. 90.1; Emammat 29; Emammat boulevard
City
Mashhad
Province
Razavi Khorasan
Postal code
9188667334
Approval date
2020-06-30, 1399/04/10
Ethics committee reference number
IR.MUMS.NURSE.REC.1399.033

Health conditions studied

1

Description of health condition studied
Intestinal obstruction
ICD-10 code
K56.69
ICD-10 code description
Other intestinal obstruction

Primary outcomes

1

Description
Coping
Timepoint
Before the intervention, discharge time and 27 days later.
Method of measurement
The Filipino Coping Strategies scale

2

Description
Stress
Timepoint
Before the intervention, 72 hours after the intervention, discharge time, 27 days after the intervention
Method of measurement
Depression, Anxiety, Stress scale DASS- 21 scale

3

Description
Anxiety
Timepoint
Before the intervention, 72 hours after the intervention, discharge time, 27 days after the intervention
Method of measurement
Depression, Anxiety, Stress scale (DASS- 21 scale)

Secondary outcomes

1

Description
The patient's weight
Timepoint
Before the intervention, at discharge time and 27 days after the intervention
Method of measurement
weight scale

2

Description
Nutrition situation indices
Timepoint
Before the intervention, at discharge time and 27 days after the intervention
Method of measurement
Patient-Generated Subjective Global Assessment

Intervention groups

1

Description
Intervention group: the intervention is the intentional presence of the holistic nurse which is based on the theories of holistic presence in three levels (physical, psychological and therapeutic) and holistic nurse's intentionality. According to this approach the nurse should start her nursing care based on the patient's trust and his/her exact needs. This research is planned in 5 holistic nursing care meetings in about 30-45 minutes. The research environment is the surgical ward, 24 hours after the surgery. In each session the researcher tries to be in an empathic relationship with the patient in which the patient would trust to the researcher. The intention to improve the patient's needs is the most important antecedent of each therapeutic relationship. Then the patient will release her emotions and tell the researcher about her/his actual needs. In this situation the researcher tries to use the holistic need assessment scale to help the patient to declare all of the needs (physical, psychological, social and spiritual needs). Then the researcher tries to sort the patient's needs from the most important to the less, and design a nursing care plan for the patient according to her/his needs. Simultaneously the researcher gives a self care education application to the patient which has all of the educational contents for the patients with bowel obstruction. The nursing care plan is unique for each patient. The intentional presence meetings will be started at the hospital and continued after discharge during one month at least 2 times in a week. It should be mentioned that the patients would give all of the routine treatments.
Category
Rehabilitation

2

Description
Control group: the patients in control group will give all of the routine cares and treatments such as monitoring vital signs, wound care, serum therapies, spacial drugs and treatments. All of the educational pamphlets would be given to the patients during the hospitalization and after the discharge. If the patient will have a colostomy, she/he would refer to a specialist nurse to learn about taking care of her/his colostomy.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Mahboubeh Kavousi
Street address
Shariati Square, begining of koohsangi Avenue
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Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
kavousim971@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Mohsen Tafaghodi
Street address
Ebne sina avenue- Near the Emam Reza Hospital, Nursing and Midwifery School
City
Mashhad
Province
Razavi Khorasan
Postal code

9137913199
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Fax
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Email
aghebatin@mums.ac.ir
Grant name
Nahid Aghebati
Grant code / Reference number
990427
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
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
Mashhad University of Medical Sciences
Full name of responsible person
Mahboubeh Kavousi
Position
post graduate student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
Bachelor
Other areas of specialty/work
Nursery
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kavousim971@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahboubeh Kavousi
Position
post graduate student
Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary

No - There is not a plan to make this available