Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Betty Neuman’s systems model application on anxiety levels of elderly people candidate colonoscopy examination.

Protocol summary

Study aim
Determining the Effect of Betty Neuman’s systems on Elderly Anxiety Levels of Candidate Colonoscopy.

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct
Samples are referred to the endoscopy department of Imam Sajad Hospital in Ramsar for outpatient colonoscopy. Marriage, employment, place of residence, economic status, insurance, level of education, cohabitation, history of chronic illness, and average score of anxiety in the two groups were matched, with a simple random sampling method in pairs and individuals in one Test and control groups will be included. So that no one is aware that they are in the test or control group. The data were collected by completing three questionnaires, so that the demographic information questionnaire, the elderly needs assessment form of the colonoscopy candidate based on the Betty Neuman model before Segal's anxiety intervention and questionnaire will be completed before and after the intervention in both the test and control groups.

Participants/Inclusion and exclusion criteria
All 60-75 year old referred to the endoscopy department؛ lack of cooperation and willingness of samples at each stage of the study

Intervention groups
Each member of the Nursing Intervention Test Group (Client Training and Counseling) will receive individual intervention based on the training needs derived from Betty Neuman's needs assessment form and members of the Routine Hospital Intervention Control Group.

Main outcome variables
improving the roles of nurses in the three levels of health, treatment and rehabilitation؛ A framework for educating and preparing elderly candidates for colonoscopy and various diagnostic procedures by health care providers using Betty Neuman system models Colonoscopy Candidate؛ Planning and Training for Increasing Care Standards Adjust the level of anxiety.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200211046461N1**
Registration date: **2020-06-12, 1399/03/23**
Registration timing: **retrospective**

Last update: **2020-06-12, 1399/03/23**
Update count: **0**

Registration date
2020-06-12, 1399/03/23

Registrant information

Name
Fatemeh Larijani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 5526 7359

Email address
fatemeh.larijani72@gmail.com

Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2019-12-21, 1398/09/30

Actual recruitment start date
2019-10-07, 1398/07/15

Actual recruitment end date
2020-01-10, 1398/10/20

Trial completion date

2020-01-10, 1398/10/20

Scientific title

The effect of Betty Neuman’s systems model application on anxiety levels of elderly people candidate colonoscopy examination.

Public title

The Effect of Betty Neuman’s systems model on Anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Elderly age range of 75-60 years Willingness to participate in research Fluency in Persian Non-use of anti anxiety and anti psychotic drugs No hearing impairment No cognitive impairment based on the AMT scale No record of severe mental crises in the past three months (such as losing close relatives) No history of endoscopy or colonoscopy The elderly are merely under a colonoscopy Obtain at least 50% of Betty Neuman’s systems model Needs Assessment score.

Exclusion criteria:

Non-cooperation of samples at each stage of the study No referral for colonoscopy

Age

From **60 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

If you receive at least 50% of the total need assessment form, you will be enrolled as a person with an educational need.Then the samples are based on variables such as age, sex, marital status, employment, residence, economic status, insurance, education, home, history of chronic illness (diabetes, hypertension, cancer, copd, etc.), And the matched anxiety score will be assigned to one of the experimental and control groups by random allocation method in both groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Elderly candidate for colonoscopy Outpatient visit the endoscopy unit of Imam Sajad Hospital in Ramsar. The researcher identifies the elderly candidate for colonoscopy after receiving approval from the University Research Council and obtaining approval from the University Ethics Committee and obtaining permission from the Imam Sajad Hospital in Ramsar, referring to the Endoscopy Unit.Then, by phone call, they will be invited to an introductory meeting and co-operation in a training class at Imam Sajad Hospital in Ramsar a week before colonoscopy. This session will explain the research outline for examples. If they wish and consent to participate in the research and to complete a written consent form, they will be asked to complete a researcher-made form of an elderly candidate for colonoscopy based on the Betty Neuman’s systems model .Individuals will be included in the study if they receive at least 50% of the total form of the needs assessment.

Placebo

Not used

Assignment

Parallel

Other design features

Individuals with at least 50 percent of the total score of the needs assessment form will participate in the study as those with educational needs. According to the steps of the Betty Neuman nursing process, the intervention will be done in four stages. Thus, in the first stage, potential and actual stressors are identified based on the needs assessment form of Betty Newman model. It should be noted that the initial evaluation will be based on the Betty Neuman model for both groups and one week before the colonoscopy, and the anxiety questionnaire will be completed by individuals in both groups. In the second stage, appropriate goals and strategies (nursing diagnoses) for nursing measures are determined by strengthening the natural and flexible defense line. In the third stage, nursing interventions (training and counseling of clients) will be implemented based on the needs of clients.In this model, the purpose of strengthening the defensive lines of nursing interventions (training and counseling) according to the needs of the elderly about the structure, sequence, characteristics of the colonoscopy unit, as well as training on defining and explaining relaxation techniques, etc. Reduces the possibility of exposure to stressors and in some cases reduces the corresponding reactions. Only in the test group, individual intervention based on the training needs derived from the needs assessment form for each elderly person will be performed for 30-30 minutes. In the present study, the needs assessment form has already been developed. Educational content related to each of the items of the needs assessment form will be developed in each of the physiological, psychological, cultural-social, evolutionary and spiritual dimensions. Given that educational needs can vary from person to person, education and counseling are tailored to the needs of the elderly. Due to the fact that the initial intervention is one week before the colonoscopy, additional training sessions will be arranged during this week as needed. The researcher's phone number is also given to the elderly so that they can receive answers to their questions by contacting the researcher. During this time, the researcher will be in link with them by phone and will be consulted if they feel the need. In the final stage, the evaluation is done. In the present study, evaluation will be performed at the beginning of the study and at the end of the intervention (before entering the colonoscopy room) by measuring the level of anxiety by completing the Segal Anxiety

Questionnaire.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Shahid Motahari Ave, Enghelab Square, Fatemeh Zahra School of Nursing and Midwifery Ramsar

City
Ramsar

Province
Mazandaran

Postal code
۴۶۹۱۷۱۴۱۴۱

Approval date
2019-07-21, 1398/04/30

Ethics committee reference number
IR.MUBABOL.HRI.REC.1398.126

Health conditions studied

1

Description of health condition studied
colonoscopy

ICD-10 code
(K00-K93)

ICD-10 code description
Diseases of the digestive system

Primary outcomes

1

Description
Percent of elderly anxiety level

Timepoint
Elderly anxiety level at the beginning of the study (before the intervention), one hour before the colonoscopy and immediately before entering the colonoscopy room after the intervention

Method of measurement
Segal Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in the study group received nursing process of Betty Neuman's theory by the researcher plus the routine hospital intervention.

Category
Prevention

2

Description
Control group1: Patients only received the routine hospital intervention.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Sajad Hospital

Full name of responsible person
Fatemeh Larijani

Street address
Shahid Motahari Ave, Enghelab Square

City
Ramsar

Province
Mazandaran

Postal code
4691714144

Phone
+98 11 5522 2033

Fax

Email
Fatemeh.larijani72@gmail.com

Web page address
http://h-imamsajad.mazums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Reza Ghadimi

Street address
Babol University of Medical Sciences, Ganj Afrooz Ave, Babol Town, Mazandaran Province, Iran

City
Babol

Province
Mazandaran

Postal code
۴۷۱۷۶۴۷۷۴۵

Phone
+98 11 3219 9592

Email
info@mubabol.ac.ir

Web page address

https://www.mubabol.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Fatemeh Larijani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Imam sajad hospital-ramsar

City

Ramsar

Province

Mazandaran

Postal code

4691151594

Phone

+98 11 5526 7359

Fax

Email

fatemeh.larijani72@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Fatemeh Larijani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Imam sajad hospital-ramsar

City

Ramsar

Province

Mazandaran

Postal code

4691151594

Phone

+98 11 5526 7359

Fax

Email

fatemeh.larijani72@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Fatemeh Larijani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Imam sajad hospital-ramsar

City

Ramsar

Province

Mazandaran

Postal code

4691191594

Phone

+98 11 5526 7359

Fax

Email

fatemeh.larijani72@gmail.com

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

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after people have not been identified.

When the data will become available and for how long

The beginning of the access period to the data files from

1399 for 6 months after the publication of the study results.

To whom data/document is available

Study data will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Any analysis on the data is allowed after obtaining the consent of the researcher.

From where data/document is obtainable

Ways of communication: Mobile number: 09115757971 ابتداEmail: fatemeh.larijani72@gmail.com

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

The respondent first receives an email from the applicant. The respondent is obliged to send the answer within 7-14 days. If the applicant needs to receive information immediately, he can receive the information he needs by contacting the respondent's mobile phone.

Comments