Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

The Effect of nursing consultation program anxiety, tolerance and Satisfaction of patients undergoing colonoscopy Imam Khomeini Hospital in Tehran in 2013-2014

Protocol summary

Summary

Patients in the intervention group (n = 37) and controls (n = 37) participated in this study and based on the type of work that is based on sampling random assignment and control groups based on the number of patient cases will be(allocation by a nurse of unit colonoscopy done who is not aware of the type of intervention) and given that waiting time per patient for colonoscopy 18-24 hours will be research in parallel with intervention samples; thus samples were then entered into the study, initially researcher first demographic questionnaire and through interviews with patients and records studies will be completed. The questionnaire contained a number of questions regarding demographic information and some questions about health and disease. Then if you have of entering the study the first researchers consent form to participate in the study, patients will be able to sign it. After you select the patient's get the satisfaction entering the study, patients entered the study and then by a second investigator who is unaware of the intervention and control groups for all subjects, including information on blood pressure, pulse and respiration per minute (before advice) and advice questionnaires of anxiety STAI If the interview is completed. Patients in the intervention group, a third researcher will consult with her bedside for 30 minutes. Individual counseling and face-to-face. The consultation, the consultation nursing and explain all the circumstances, including before, during and after colonoscopy is including training preparation before the procedure (diet, drugs, etc.), during a colonoscopy (a complete explanation about what will be done during the colonoscopy)patient raise awareness about the benefits and risks of giving the patient an opportunity to express feelings, questions, selecting appropriate ways to reduce anxiety and increase tolerance, procedures, and respond to questions posed by the patient. Patients in the control group, all of these steps can be done in consultation with the patient. The next day, the researcher prior to colonoscopy for people of all data including blood pressure, pulse and respiration and the minutes STAI state anxiety questionnaire is to be completed. Patient tolerance of colonoscopy and Satisfaction scale, the level of cooperation during colonoscopy, comfort level and pain level completion rates measure by which the researcher is unaware of the experimental and control groups will be compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022011936N2**
Registration date: **2013-07-05, 1392/04/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-07-05, 1392/04/14

Registrant information

Name
Mahmoud Amiri
Name of organization / entity
Shahed University
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Student Research Center, Shahed University

Expected recruitment start date
2013-04-30, 1392/02/10
Expected recruitment end date
2014-06-15, 1393/03/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of nursing consultation program anxiety, tolerance and Satisfaction of patients undergoing colonoscopy Imam Khomeini Hospital in Tehran in 2013-2014

Public title
The effect of nursing consultation on anxiety, tolerance and satisfaction in patients undergoing colonoscopy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: age between 18 -75 years old; the ability to understand the Persian language; lacking a history previous colonoscopy; lack known history of psychological problems or anxiety disorders (According to the survey patient records); lack of use sleep medications and sedatives on the day before colonoscopy; lack of severe pain due to the nature of the disease (for example cancer); lack of narcotic addiction or strong analgesics and absence of disease or a history of hypertension and antihypertensive drugs. Exclusion criteria: canceled on the day of colonoscopy to determine the cause of non-anxious patients and patient withdrew from participating the study.
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahed University
Street address
Tehran - Gulf Freeway - opposite the shrine of Imam Khomeini
City
Tehran
Postal code
3319118651
Approval date
2013-04-10, 1392/01/21
Ethics committee reference number
168149/41

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Anxiety
Timepoint
Before intervention - a day after the intervention (before the procedure)
Method of measurement
Spielberger standard questionnaire

Secondary outcomes

1

Description
Tolerance
Timepoint
After Colonoscopy
Method of measurement
The Likert scale measure

2

Description
Satisfaction
Timepoint

After Colonoscopy

Method of measurement

Numerical scale (1 least satisfied - 10 most satisfied)

3

Description

Comfort

Timepoint

After Colonoscopy

Method of measurement

Comfort numerical scale (1 lowest Comfort, 10 maximum comfort level)

4

Description

Cooperation rates during colonoscopy

Timepoint

After Colonoscopy

Method of measurement

Numerical scale contribution (1 co lowest, 10 the highest level of cooperation)

5

Description

Pain

Timepoint

After Colonoscopy

Method of measurement

numeric pain scale (1 least amount of pain, 10 maximum pain)

Intervention groups

1

Description

Intervention group = received 30 minutes of nursing counseling program that includes training preparations in the days before colonoscopy -training what done colonoscopy - Basic skills training techniques to reduce anxiety

Category

Behavior

2

Description

Control group = received routine part of program

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Najm Zadeh Zahra

Street address

Tehran - Bagher Khan Street - Imam Khomeini Hospital Complex

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Kyasalary Zahra - Deputy Director of Research and Technology

Street address

Tehran - Gulf Freeway - Opposite the shrine of Imam Khomeini

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Mahmoud Amiri

Position

Undergraduate Nursing students

Other areas of specialty/work

Street address

Tehran - Vali Asr Street - Before the of Taleghani Crossroad- Alley Rhymzadh - No. 6

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Person responsible for scientific inquiries

Contact
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Shahed University
Full name of responsible person
Majideh heravi karimovi
Position
PhD Nursing
Other areas of specialty/work
Street address
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City
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Postal code
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Fax
+98 21 6641 8580
Email
heravi@shahed.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Mahmoud Amiri
Position
Undergraduate Nursing students
Other areas of specialty/work
Street address
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty