

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of nursing counseling on the anxiety level of elderly patients undergoing upper gastrointestinal endoscopy

Protocol summary

Study aim

Determination of the effect of Nursing Counseling on the anxiety level of elderly patients undergoing endoscopy

Design

A randomized, controlled clinical trial with a parallel group design of 198 patients, enrolled between April 2020 and July 2020.

Settings and conduct

This study will be performed on 198 elderly patients who are candidates for the upper gastrointestinal endoscopy and refer to Imam Khomeini Hospital in Bandar Turkman and meet the inclusion criteria. All the patients will receive routine care before endoscopy, but the patients in the intervention group will consult based on the educational package prepared for this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 60 years old, Upper gastrointestinal endoscopy is prescribed at least one day in advance, No previous endoscopic history, Having the ability to establish verbal communication, Not taking corticosteroid drugs, Willingness to participate in the study. Exclusion criteria: Using hypnotic and sedative drugs before endoscopy, addiction, Known case of psychiatric disease, Having any lesion or ulcer in the mouth.

Intervention groups

Intervention group: The patients in the intervention group will be received 30 minutes face to face educational counseling on the night before endoscopy. The educational counseling will be done based on the content of the booklet which produced by researchers and then the booklet is given to the patient. Control group: The patients in the control group will receive the pre-endoscopic preparations and routine care

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181030041501N1**

Registration date: **2020-05-08, 1399/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-08, 1399/02/19**

Update count: **0**

Registration date

2020-05-08, 1399/02/19

Registrant information

Name

sohrab kor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3443 2486

Email address

nurse.kor@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nursing counseling on the anxiety level of elderly patients undergoing upper gastrointestinal endoscopy

Public title

The effect of nursing counseling on the anxiety level of elderly before endoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years old Upper gastrointestinal endoscopy is prescribed at least one day in advance No previous endoscopic history Having the ability to establish verbal communication Not taking corticosteroid drugs Willingness to participate in the study

Exclusion criteria:

Using hypnotic or sedative drugs before endoscopy Addiction Known case of psychiatric disease Having any lesion or ulcer in the mouth

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **198**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Patients will be randomly and equally (n=99) allocated to two intervention and control groups by a nurse, working in the inpatient ward, who has been trained in the random allocation of patients. Random allocation will be done as follows; first, we will consider two AB and BA combinations designated with the code names 1 and 2, respectively by throwing a homogeneous hexagon. If the odd number occurs, we will write down combination 1 (AB) and If the even number occurs, we will write down combination 2 (BA). This step will be repeated 99 times to create a random sequence of twin blocks. Then we randomly assign the patients to the members of this sequence (A and B). For example, the sequence of random blocks can be as follows: BABAABABABBA... Afterwards, by throwing a flawless coin, the patients assigned to the letter A will fall into the intervention group and the patients assigned to the letter B will fall into the control group.

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 Committee of Golestan University of Medical Sciences

Street address

Deputy of Research and Technology, Golestan University of Medical Sciences, Hirkan Boulevard, Gorgan, Iran

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2018-12-31, 1397/10/10

Ethics committee reference number

IR.GOUMS.REC.1397.200

Health conditions studied

1

Description of health condition studied

The anxiety of elderly patients undergoing upper gastrointestinal endoscopy

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

Level of anxiety

Timepoint

Before intervention and a day after intervention (before endoscopy)

Method of measurement

Spielberger Anxiety Inventory

Secondary outcomes

1

Description

Level of salivary cortisol

Timepoint

Before intervention and a day after intervention (before endoscopy)

Method of measurement

Saliva cortisol measurement kits, made by Diametra in

Italy using ELISA method

2

Description

Blood pressure

Timepoint

Before intervention and a day after intervention (before endoscopy)

Method of measurement

The Sazgan Gostar portable monitoring system, Vista Model, made in Iran..

3

Description

Heart rate

Timepoint

Before intervention and a day after intervention (before endoscopy)

Method of measurement

The Sazgan Gostar portable monitoring system, Vista Model, made in Iran.

4

Description

Respiratory rate

Timepoint

Before intervention and a day after intervention (before endoscopy)

Method of measurement

The Sazgan Gostar portable monitoring system, Vista Model, made in Iran.

5

Description

Arterial blood saturation percentage

Timepoint

Before intervention and a day after intervention (before endoscopy)

Method of measurement

The Sazgan Gostar portable monitoring system, Vista Model, made in Iran.

Intervention groups

1

Description

Intervention group: The patients in the intervention group will be received 30 minutes face to face educational counseling on the night before endoscopy. The educational counseling will be done based on the content of the booklet which produced by researchers and then the booklet is given to the patient.

Category

Other

2

Description

Control group: The patients in the control group will receive the pre-endoscopic preparations and routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Ali Bidari

Street address

Imam Khomeini Hospital, Arekhi Boulevard, Bander Torkeman city, Golestan province

City

Bander Torkeman

Province

Golestan

Postal code

4891674811

Phone

+98 17 3442 3091

Fax

+98 17 3442 4442

Email

nurse.kor@gmail.com

Web page address

<http://goums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Reza Honarvar

Street address

Deputy of Research and Technology, Golestan University of Medical Sciences, Hirkan Bulvar, Gorgan

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3245 1660

Fax

+98 17 3245 1657

Email

honarvar@goums.ac.ir

Web page address

http://goums.ac.ir/index.php?slc_lang=fa&sid=12

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Sohrab Kor
Position
Ms student of geriatric nursing
Latest degree
Bachelor
Other areas of specialty/work
Geriatric nursing
Street address
Faculty of Nursing and Midwifery, Golestan University
of Medical Sciences, Hirkan Bulvar, Gorgan
City
Gorgan
Province
Golestan
Postal code
4917136536
Phone
+98 17 3217 5338
Fax
+98 17 3245 5171
Email
Nurse.kor@gmail.com
Web page address
<http://goums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Shohreh Kolagari
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursing
Street address

Faculty of Nursing and Midwifery, Golestan University
of Medical Sciences, Hirkan Bulvar, Gorgan

City
Gorgan
Province
Golestan
Postal code
4917136536
Phone
+98 17 3245 6900
Fax
+98 17 3245 5171
Email
dr.kolagari@goums.ac.ir
Web page address
<http://goums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Sohrab Kor
Position
Ms student of geriatric nursing
Latest degree
Bachelor
Other areas of specialty/work
Geriatric nursing
Street address
Faculty of Nursing and Midwifery, Golestan University
of Medical Sciences, Hirkan Bulvar, Gorgan
City
Gorgan
Province
Golestan
Postal code
4917136536
Phone
+98 17 3245 6900
Fax
+98 17 3245 5171
Email
nurse.kor@gmail.com
Web page address
<http://goums.ac.ir>

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 data will be shared after identifying people.

When the data will become available and for how long

Six months after publishing, the results of the data file will be presented.

To whom data/document is available

Data will be available to researchers working in academic institutions.

Under which criteria data/document could be used

Meta analysis on data are allowed.

From where data/document is obtainable

Please contact the person responsible for the study.

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

Access to data through e-mail after obtaining permission from researchers is possible.

Comments

To receive information, please email both the following addresses: kolagari_gorgan@yahoo.com; dr.kolagari@goums.ac.ir