

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of training on fear and anxiety of patients undergoing colonoscopy

Protocol summary

Study aim

The effect of the education on fear and anxiety in patients undergoing colonoscopy in hospitals of Kerman city, 2017

Design

Clinical trial with control group, patients in intervention group on pairs and control group on days. The sample size is 90 patients.

Settings and conduct

Patients in the intervention group will be instructed, but the control group will have routine care. In order to conduct research, a researcher will be presenting a colonoscopy candidate in the department of gastrointestinal and internal wards of Kerman hospitals before the colonoscopy on the day before and after expressing the research goals and having the conditions for entering the study and written consent for participation in the research. Will do research. Demographic information questionnaire, Spielberger anxiety inventory and colonoscopy fear questionnaire will be filled in by the researcher by interview method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: a Permission to perform colonoscopy for a colonoscopy, aged 18 to 80 years of Iranian nationality. Exit criteria: The use of sleep medications quiet section, Having aches, Drug addiction or strong analgesics, Use of sedative medications and colonoscopy history.

Intervention groups

Patients undergoing colonoscopy have paused days in the intervention group and in the control group days. The intervention group is being trained, but the control group will have routine care.

Main outcome variables

The amount of anxiety; fear In patients with colonoscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160914029817N5**

Registration date: **2018-06-02, 1397/03/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

Esmat Nuhi

Name of organization / entity

Kerman University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5220

Email address

e_nuhi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of training on fear and anxiety of patients undergoing colonoscopy

Public title

The effect of training on fear and anxiety of patients undergoing colonoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having an order for colonoscopy aged 18 to 80 years old, and Iranian specialty

Exclusion criteria:

Use of sleepy and sedative medicines having pain addiction or strong analgesics using sedative medications colonoscopy history

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by random allocation method to control and intermediate group, Random unit of the sample that the intervention group is placed on a couple of days and a control group on an individual's day.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

There are 45 patients in the intervention group on pair days and 45 patients in the control group on days

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of kerman university of Medical Sciences

Street address

Kerman, the beginning of the Compus University of Medical Sciences, beginning around Seven Gardens Alavi, kerman Boulevard Haft Bagh Alavi, Medical

Sciences Campus Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2018-04-03, 1397/01/14

Ethics committee reference number

ir.kmu.rec.1396.2467

Health conditions studied

1

Description of health condition studied

Patients with colonoscopy candidates

ICD-10 code

K55-k64

ICD-10 code description

Other diseases of intestines

Primary outcomes

1

Description

Anxiety Score in Spielberg's Questionnaire

Timepoint

Before intervention and after intervention

Method of measurement

Spilberger State-Trait Anxiety Inventory

Secondary outcomes

1

Description

Measure the amount of fear

Timepoint

Before intervention and after intervention

Method of measurement

Colonoscopy Fear Questionnaire

Intervention groups

1

Description

Intervention group: Patients with colonoscopy candidates are trained in the intervention group on pair days. The purpose of educational intervention is to provide information on colonoscopy, the importance and benefits of using it, an explanation of all stages before, during and after colonoscopy, pre-colonoscopy training, an appropriate position during the test, an opportunity to express feelings And questions, answers to possible questions, and deep breathing training for patients.

Category

Behavior

2

Description

The control group, only routine actions are performed on individual days.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Nadere Baniyadi

Street address

Kerman, Imam Khomeini highway

City

Kerman

Province

Kerman

Postal code

7616913911

Phone

+98 34 3132 8000

Fax

+98 34 3325 7770

Email

afzalih@kmu.ac.ir

Web page address

http://kmu.ac.ir

2

Recruitment center

Name of recruitment center

Great Prophet hospital

Full name of responsible person

Nadere Baniyadi

Street address

Kerman, Abu hamed street

City

Kerman

Province

Kerman

Postal code

7614749549

Phone

+98 34 3226 6595

Fax

+98 34 3325 7770

Email

nadere.baniyadi@gmail.com

Web page address

http://tamin.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Abbas Pardakhty

Street address

Compus University of Medical Sciences rdens Alavi,
Research Management, St. Ibn Sina, Tahmasebabad
Crossroads.

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 3855

Fax

+98 34 3226 3857

Email

abpardakhty@kmu.ac.ir

Web page address

http://vcrt.kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Nadere Baniyadi

Position

Master of Medical Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Campus University of Medical Sciences, beginning
around Seven Gardens Alavi, Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5219

Fax

+98 34 3132 5218

Email

nadere.baniasadi@gmail.com

Web page address

http://kmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr.Esmat.Nuhi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Campus University of Medical Sciences beginning around Seven Gardens Alavi;Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5220

Fax

+98 34 3132 5218

Email

e_nuhi@kmu.ac.ir

Web page address

http://kmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Nadere Baniasadi

Position

Master of Medical Surgery Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Campus University of Medical Sciences, beginning around Seven Gardens Alavi, Kerman

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3246 3507

Fax

+98 34 3132 5219

Email

nadere.baniasadi@gmail.com

Web page address

http://kmu.ac.ir

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

Failure to complete the plan

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