

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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 Baniasadi

**Street address**

Kerman, Imam Khomeini highway

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afzalih@kmu.ac.ir

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2

**Recruitment center**

**Name of recruitment center**

Great Prophet hospital

**Full name of responsible person**

Nadere Baniasadi

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nadere.baniasadi@gmail.com

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**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  
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abpardakhty@kmu.ac.ir

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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 Baniasadi

**Position**

Master of Medical Surgical Nursing

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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

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## Person responsible for scientific inquiries

**Contact**  
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Kerman University of Medical Sciences  
**Full name of responsible person**  
Dr.Esmat.Nuhi  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
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## Person responsible for updating data

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**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**  
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