

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effect of educational intervention on anxiety of patients undergoing colonoscopy

Protocol summary

Summary

The objective of this study is to determine the Effect of educational intervention on anxiety of patients undergoing colonoscopy. In this quasi- experimental study in colonoscopy Unit Of Shiraz University, 120 patients are scheduled to undergo colonoscopy. The patients are randomly allocated to experimental or control group. The patients in the experimental group receive intervention of nursing consultation lasted 30 minutes about colonoscopy before day, while control group does not receive any intervention. Anxiety level (recorded by spiel burg questioner) and vital signs are measured in both groups before intervention and on the colonoscopy day (immediately before the procedure). During the colonoscopy their satisfaction are measured by VAS

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410268505N10**

Registration date: **2015-02-11, 1393/11/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-11, 1393/11/22

Registrant information

Name

Seyed Saeed Najafi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1727 7445

Email address

najafisa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-09-07, 1393/06/16

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of educational intervention on anxiety of patients undergoing colonoscopy

Public title

Effect of educational intervention on anxiety of patients undergoing colonoscopy, referred to endoscopy clinical of Shiraz hospital medical sciences 1393

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Having order of colonoscopy at least one day before the procedure; Age between 18 and 80 years old; Ability to speak and understanding Persian language; no problem to see the VAS; no previous colonoscopy; no order of emergency colonoscopy; no History of psychological disease or anxiety disorder; no consumption of opiate or sedative drugs; no severe pain due to nature of disease; no addiction to opium or narcotics; no hypertension or using anti hypertensive drugs Exclusion criteria: canceling the colonoscopy due to any reason except for patient's anxiety; no willingness

to participate in the

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Research Ethics Committee of Shiraz
University of Medical Sciences

Street address

Central building of Shiraz University of Medical
Sciences, Zand street, Shiraz

City

shiraz

Postal code

71345-1978

Approval date

2014-09-06, 1393/06/15

Ethics committee reference number

93-203316

Health conditions studied

1

Description of health condition studied

colonoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety

Timepoint

One day before Endoscopy(before consultation) and
immediately before Endoscopy

Method of measurement

Spiel berg questioner

Secondary outcomes

1

Description

Patient's satisfaction

Timepoint

WHILE colonoscopy

Method of measurement

Visual Analog scale

2

Description

Blood pressure

Timepoint

One day before colonoscopy (before educational) and
immediately before colonoscopy

Method of measurement

indicator

3

Description

Pulse

Timepoint

One day before colonoscopy (before educational) and
immediately before colonoscopy

Method of measurement

By researcher

4

Description

Respiratory rate

Timepoint

One day before colonoscopy (before consultation) and
immediately before colonoscopy

Method of measurement

By researcher

Intervention groups

1

Description

Intervention group: educational for half an hour one day
before colonoscopy. This educational is including
instruction about needing preparation pre colonoscopy
(such as diet, drugs,...), explanation about stages
pre(instruction necessary preparations), in(explanation
about What will happen during colonoscopy)) and
after(explanation about the probable problems that will
meet after colonoscopy) colonoscopy. It increase patient
knowledge about colonoscopy and its advantages and

probable risks and allow to patient that express his sensations and questions and answering the questions of patient.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

colonoscopy Unit Of Shiraz University of Medical Sciences

Full name of responsible person

Seyed Saeed Najafi

Street address

Hazrat-e-Fatimah nursing and midwifery college, Namazi hospital, Namazi square

City

shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice-Chancellor for Research, Shiraz University of Medical Sciences

Full name of responsible person

seyed Baser Hashemy

Street address

Square Namazi, Shiraz University Medicine Sciences.

City

shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-Chancellor for Research, Shiraz University of Medical Sciences

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**

Fatimah(PBUH) School of Nursing and Midwifery, Shiraz University of Medical Science Namazi Square

Full name of responsible person

Rasol Mohamadbigie

Position

Master of science

Other areas of specialty/work**Street address**

Fatemeh(PBUH) School of Nursing and Midwifery, Shiraz University of Medical Science Namazi Square

City

Shiraz

Postal code**Phone**

+7 138315561

Fax**Email**

mohamadbigie@sums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz university of medical science

Full name of responsible person

Seyed Saeed Najafi

Position

MS in nursing - Faculty

Other areas of specialty/work**Street address**

Fatimah(PBUH) School of Nursing and Midwifery, Shiraz University of Medical Science Namazi Square

City

Shiraz

Postal code

71345-1978

Phone

+91 61613828

Fax**Email**

s_najafi44@yahoo.com najafisa@sums.ac.irr

Web page address**Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Seyed Saeed Najafi

Position

MS in nursing - Faculty

Other areas of specialty/work**Street address**

Shiraz University of Medical Science

City

Shiraz

Postal code**Phone**

+7 136474254

Fax**Email**

s_najafi44@yahoo.com; najafisa@sums.ac.irr

Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty