

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of psychological preparation on the anxiety level before colonoscopy in outpatients referred to Golestan hospital of Ahvaz

Protocol summary

Study aim

The aim of this study was to evaluate the efficacy of psychological effect on the anxiety level of preparation before colonoscopy in patients presenting to Golestan Hospital

Design

This study is a double-blind clinical trial consisted of 80 colonoscopy candidate patients that randomly divided into two groups(40 patients in each group) ; Intervention and control

Settings and conduct

The study will be carried on patients presenting to Golestan Hospital in the colonoscopy unit. Patients and nurses will be not informed that every patient has taken which consultation

Participants/Inclusion and exclusion criteria

Patients aged 18-80 years, Farsi language conversation skills, ability to communicate verbally, the lack of previous experience in colonoscopy, having were included. While, patients with the risk of dementia, mental retardation, obvious physical problems that interfere in the consultation, a history of major psychiatric disorders and decline to participate were excluded from the study

Intervention groups

In this study, firstly, the clinical, demographic, questionnaire was completed based on information obtained from the patient as well as the contents of the file, including age, education, marital status, occupation, income level, gender, smoking history and family history of colonoscopy, the presence of other commodities, including high blood pressure, high blood lipids, diabetes, chronic renal failure and pulmonary disease. Then, to measure the amount of the patient's anxiety, Spielberger State-Trait Anxiety Inventory (STAI) was used. STAI includes separate self-assessment scales to measure the state and trait anxiety

Main outcome variables

Patient's anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170308032961N2**

Registration date: **2018-04-22, 1397/02/02**

Registration timing: **retrospective**

Last update: **2018-04-22, 1397/02/02**

Update count: **0**

Registration date

2018-04-22, 1397/02/02

Registrant information

Name

Hadis Mehregan nasab

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8317

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mehregan.h@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2017-04-04, 1396/01/15

Actual recruitment start date

2016-04-03, 1395/01/15

Actual recruitment end date

2017-04-04, 1396/01/15

Trial completion date

empty

Scientific title

The effect of psychological preparation on the anxiety level before colonoscopy in outpatients referred to Golestan hospital of Ahvaz

Public title

Effect of psychological preparation on the anxiety level before colonoscopy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

18-80 years old Farsi language conversation skills Ability to communicate verbally Lack of previous experience in colonoscopy

Exclusion criteria:

Dementia Mental retardation Obvious physical problems that interfere with the consultation A history of major psychiatric disorders Decline to participation

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was based on the method of 4-way permuted blocks

Blinding (investigator's opinion)

Double blinded

Blinding description

The nurses were not informed that every patient has taken which consultation

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan BLV

City

Ahvaz

Province

Khouzestan

Postal code

6455134358

Approval date

2015-10-17, 1394/07/25

Ethics committee reference number

IR.AJUMS.REC.1394.415

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes**1****Description**

Anxiety

Timepoint

3-5 days before colonoscopy, After psychological preparation

Method of measurement

Spielberger State-Trait Anxiety Inventory (STAI) questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Psychological preparation was performed by a psychiatric resident in a separate room 2 to 3 hours before colonoscopy; after evaluating the concerns, the amount of information and the beliefs of the patients of colonoscopy in three domains: information, cognitive and behavioral the interventions were done as follows: Control Information: At this stage the patient inaccurate information is corrected and enough .1 explanation of additional information about how to perform a colonoscopy, time, duration and .general conditions of the process was given to the patient 2. Cognitive control: According to cognitive distortions found in patients, cognitive control was done for the patient (e.g., patient attention to the benefits of surgery and its positive tips instead focus on its unpleasant and negative aspects). 3. Behavioral control: the patient was given the behavioral control methods, including special breathing exercises, distraction

techniques and an explanation on how the patient's knowledge-based colonoscopy to use these methods in the event of the occurrence of anxiety while doing a colonoscopy.

Category

Behavior

2

Description

Control group: In the control group, 0 to 3 hours before the colonoscopy, the intervention will be done and more neutral content (properties of fruits and vegetables) that was prepared in the pamphlet, will be given to control groups, and no other intervention will be done

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Hadis Mehregan

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ali.khosravi70@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

Full name of responsible person

Mohammad Badvi

Street address

Golestan

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice Chancellor for Research, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

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

Ahvaz University of Medical Sciences

Full name of responsible person

Hadis Mehregan Nasab

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

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Latest degree

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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

There is no further information

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

Not applicable

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

Primary outcome measure will be available

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Only available for people working in academic institutions

Under which criteria data/document could be used

For meta-analysis study

From where data/document is obtainable

Email

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

Requested that by email and one week later, the data will be sent

Comments