

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of psychological preparation on the level anxiety before upper gastrointestinal endoscopy

Protocol summary

Summary

In a randomized clinical trial 96 patients who were referred to gastroenterology clinic of Ahvaz Golestan Hospital were selected. According to random number table, patients were divided into two groups of control and intervention, that each group has 48 members. After the study was explained to the patients, they were asked to fill out the consent form. After the inclusion and exclusion criteria were taken into account, the patients were randomly divided into an experimental and a control group, each of which included 48 patients. Inclusion criteria such as age of 18-80 years, participants should able to communicate, and can speak Farsi, lack of conduction of EGD before and Exclusion criteria like having cognitive problem, and if they had history of major psychological disorder and cognitive problem, they were excluded. This study is open-label and categorize in 2-3 trial phase. Aim of this study is to determine state and trait anxiety and compare them in intervention and control group. A Spielberg questionnaire for measuring level of anxiety was used and filled out by patients in 2 times. The first time when patients referred to the gastroenterology clinic for endoscopy that represents the basic anxiety and the second time one hour before endoscopy (after intervention). For the experimental group, after the questionnaire was completed in the first phase, psychological preparation was carried out for the patients 2-3 hours before endoscopy. After their anxiety, information, and beliefs about endoscopy conduction were assessed, the intervention was carried out in three areas: Information control, Cognitive and Behavioral control (special breath exercises, swallowing training, and distraction technique). The same time, pamphlets (properties of fruits and vegetables) gave to control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091020739N2**

Registration date: **2016-05-17, 1395/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-17, 1395/02/28

Registrant information

Name

Forouzan Behroozina

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3038

Email address

behrouzian-f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-06-20, 1393/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of psychological preparation on the level anxiety before upper gastrointestinal endoscopy

Public title

Comparison between the effects of psychological preparation and no preparation on anxiety level in patients who are candidate for upper gastrointestinal intervention

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 80-18 years; the language Farsi; the ability to communicate verbally; with no history of previous upper endoscopy; a consent to enter the scheme. Exclusion criteria: the risk of dementia; mental retardation; distinctive physical problems that interfere consultation in the history of major psychiatric disorders; that the patients is not cooperative.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

randomization was done by random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Farvardin Blvd, Golestan Ave, Ahvaz

City

Ahvaz

Postal code

6135715794

Approval date

2015-06-20, 1394/03/30

Ethics committee reference number

IR.AJUMS.REC.1394.129

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F40,F41,F4

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

State Anxiety

Timepoint

Before intervention- After intervention

Method of measurement

Spielberg questioner

2

Description

Trait Anxiety

Timepoint

Before intervention- After intervention

Method of measurement

Spielberge questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: A Spielberg questionnaire for measuring level of anxiety was used and filled out by patients in 2 times. The first time when patients referred to the gastroenterology clinic for endoscopy that represents the basic anxiety and the second time one hour before endoscopy (after intervention). For the experimental group, after the questionnaire was completed in the first phase, psychological preparation was carried out for the patients 2-3 hours before endoscopy. After their anxiety, information, and beliefs about endoscopy conduction were assessed, the intervention was carried out in three areas: Information control, Cognitive and Behavioral control (special breath exercises, swallowing training, and distraction technique

Category

Behavior

2

Description

For control group some general information about fruits and vegetable in pamphlets form have been placed at

their disposal to study, another intervention do not be.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Forouzan Behrouzian

Street address

Ahvaz Golestan Blvd

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Frouzan Behrouzian

Street address

Ahvaz Golestan Hospital

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Position

Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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Position

Assistant Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty