Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of family members presence on anxiety of patients that candidates for endoscopy

Protocol summary

Summary

Objective: provide the simple, cheap and available solution to reduce anxiety in patients undergoing endoscopy and reduction of statistically significant in refusing to do (high stress). Design: randomized, triple blind, single-center, one phase of clinical trial. Study population: The inpatient and outpatient endoscopy candidates in Modarres hospital in saveh city. The main criteria for inclusion: desire of participate for taking part in the study; having ordered endoscopy; lack of experience in educational courses (skills, problem solving, critical thinking, emotional intelligence, stress management techniques and yoga) in the last 6 months; not something new crisis like the death of first-degree relative; divorce in the past 6 months; no history of psychological problems or anxiety disorders diagnosed; having undergone previous endoscopy; no addiction drugs, alcohol; lack of sedation drugs consumption during the study. Exclusion criteria: diagnosis of mental illness in person during the study; lack of cooperation necessary to complete a questionnaire; Dissuasion of participate in research. Sample size: One hundred six, with risk of samples loss. Intervention or interventions: the presence of family members at the bedside, during endoscopy and completed the questionair by all patients. Intervention time: During endoscopy (and the individual patient's bedside). The main outcome: to reduce fear and anxiety related to endoscopy and decrease significant statistics in relation to the refusal to do so.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017011931522N2**
Registration date: **2017-02-18, 1395/11/30**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-02-18, 1395/11/30

Registrant information

Name
Vahid Naseri Salahshour
Name of organization / entity
Arak University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 86 3417 3505
Email address
v.naserisalahshour@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Saveh University of Medical Science

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family members presence on anxiety of patients that candidates for endoscopy

Public title

The presence of family members in reducing anxiety of endoscopic procedure

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: willingness of participate; the ability to read and write; having ordered endoscopy; endoscopy appropriate diagnosis by a specialist; lack of educational experience in problem solving, critical thinking, emotional intelligence methods stress management and yoga in the past 6 months; not something new crisis like the death of first-degree relative; divorce in the past 6 months; no history of psychological problems or anxiety disorders diagnosed; having undergone previous endoscopy; no addiction drugs, alcohol; lack of sedation drugs consumption during the study. Exclusion criteria: diagnosis of mental illness in person during the study; lack of cooperation necessary to complete a questionnaire; Dissuasion of participate in research

Age

From **19 years** old to **79 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The first patient in the intervention group and randomly assigned one-to-one (one of) the control and intervention groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Saveh University of Medical Sciences

Street address

Saveh, SHariati st, Madar Sq, Saveh University of Medical Sciences

City

Saveh City

Postal code

3918698786

Approval date

2016-06-01, 1395/03/12

Ethics committee reference number

IR.SAVEHUMS.REC139429

Health conditions studied

1

Description of health condition studied

Endoscopy

ICD-10 code

Y60.4, Y61

ICD-10 code description

During endoscopic examination

Primary outcomes

1

Description

The anxiety of endoscopy

Timepoint

The hidden anxiety questionaire (Two days after the intervention in two groups) / The revealed anxiety (Immediately During the endoscopy room and in the presence of a family members)

Method of measurement

State and Trait Anxiety Inventory (STAI)

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention Group1: The intervention group during endoscopy, one of the family members of the patient's presence in bedside and the patients immediately before endoscopy complete the spielberger anxiety questionnaire

Category

Prevention

2

Description

Control group: In the control group, the plain Spiel Berger anxiety questionnaire during the endoscopy after entrance to room and without the presence of family members of the patient's bedside is completed by the patients. The hidden Spiel Berger anxiety questionnaire two days after treatment is completed by two group's

samples

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Endoscopy Unit of Moddares Hospital, Saveh University of Medical Sciences

Full name of responsible person

vahid naseri salahshour, MSc of Nursing Education (Medical - Surgical Field)

Street address

Saveh, Motahhari St, Modarres Sq, Modarres Blv, Modarres Hospital

City

Saveh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Saveh University of Medical Sciences

Full name of responsible person

Hamidreza Baradaran, Vice Chancellor for research of Saveh University of Medical Sciences

Street address

Saveh, SHariati st, Madar Sq, Saveh University of Medical Sciences

City

Saveh

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 of Saveh 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

Saveh University of Medical Sciences

Full name of responsible person

vahid naseri salahshour

Position

MSc of Nursing Education in Medical Surgical Field

Other areas of specialty/work

Street address

Saveh, SHariati st, Madar Sq, Saveh University of Medical Sciences

City

Saveh

Postal code

9177899191

Phone

+98 86 4230 1291

Fax

-

Email

v.naserisalahshour@arakmu.ac.ir; vahidnaseri1994@yahoo.com

Web page address

-

Person responsible for scientific inquiries

Contact

Name of organization / entity

Saveh University of Medical Sciences

Full name of responsible person

vahid naseri salahshour (MSc of Nursing Education in Medical Surgical Field)

Position

MSc of Nursing Education in Medical Surgical Field

Other areas of specialty/work

Street address

Saveh, SHariati st, Madar Sq, Saveh University of Medical Sciences

City

Saveh

Postal code

39148-34438

Phone

+98 86 4230 1291

Fax

-

Email

v.naserisalahshour@arakmu.ac.ir; vahidnaseri1994@yahoo.com

Web page address

-

Person responsible for updating data

Contact

Name of organization / entity

Saveh University of Medical Sciences

Full name of responsible person

vahid naseri salahshour (MSc of Nursing Education in Medical Surgical Field)

Position

MSc of Nursing Education in Medical Surgical Field
Other areas of specialty/work
Street address
Saveh, SHariati st, Madar Sq, Saveh University of Medical Sciences
City
Saveh
Postal code
39148-34438
Phone
+98 86 4230 1291
Fax
-
Email
v.naserisalahshour@arakmu.ac.ir; vahidnaseri1994@yahoo.com
Web page address
-

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