

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

: The Effect Of Virtual Reality On Anxiety in Patients Undergoing Upper Gastrointestinal Endoscopy

Protocol summary

Study aim

The present study will be aimed to investigate the effects of VR technology on anxiety in patients undergoing endoscopy.

Design

In this research, the samples were selected by a goal-based method of 60 people and then assigned randomly to two groups of intervention (30 people) and control (30 people).

Settings and conduct

The inpatient and outpatient endoscopy candidates in Modarres hospital in Kashmar city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having an order for the upper gastrointestinal endoscopy Age between 30 and 60 years No history of previous endoscopy Not having an emergency endoscopy Do not take drowsy and sedative medicines Not having severe pain due to the nature of the disease (such as cancer) No drug addiction or strong analgesic Exclusion criteria: Lack of hearing or visual impairment Create intense anxiety at each stage of the study

Intervention groups

After obtaining written informed consent for participation in this research, demographic information questionnaire and Spielberger's revealing anxiety scale questionnaire containing 20 quadratic questions were completed in two groups before intervention, then the intervention group faced with virtual reality as follows: That is, while glasses are placed on the person's eyes that you know from the vast viewpoint, and provides him with a good view of the eye. The tool used for virtual reality technique is a virtual reality headset device that displays a simple film about endoscopy and nature film with high quality waterfall images and sound in a 15-minute interval for the pre-endoscopic test group. Then the anxiety is re-evaluated .in The end, data will analyzed by statistic tests using spss.

Main outcome variables

To reduce fear and anxiety related to endoscopy and decrease significant statistics in relation to the refusal to do so.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180529039903N1**

Registration date: **2018-07-16, 1397/04/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-16, 1397/04/25**

Update count: **0**

Registration date

2018-07-16, 1397/04/25

Registrant information

Name

Tahmine Ghasimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5523 6303

Email address

ghasimi.t@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
: The Effect Of Virtual Reality On Anxiety in Patients Undergoing Upper Gastrointestinal Endoscopy

Public title
: The Effect Of Virtual Reality On Anxiety in Patients Undergoing Upper Gastrointestinal Endoscopy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having an order for the upper gastrointestinal endoscopy
Age between 30 and 60 years
No history of previous endoscopy
Not having an emergency endoscopy
Do not take drowsy and sedative medicines
Mental consciousness and non-mental disorders (based on medical records)
Not having severe pain due to the nature of the disease (such as cancer)
No drug addiction or strong analgesic
Failure to record a new crisis, such as the death of a first-degree relative in the past six months
Lack of hearing or visual impairment
Exclusion criteria:
Unwillingness to continue to participate in the study for any reason
Create intense anxiety at each stage of the study

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research, the samples were selected by objective method and then assigned Simple randomization to intervention and control groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethnical Committee of Gonabad University of Medical Sciences
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Approval date
2017-09-27, 1396/07/05
Ethics committee reference number
IR.GMU.REC.1396.67

Health conditions studied

1

Description of health condition studied
Anxiety
ICD-10 code
F06.4
ICD-10 code description
Organic anxiety disorder

Primary outcomes

1

Description
Anxiety
Timepoint
before and after intervention
Method of measurement
STAI

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, the tool used for virtual reality technique is a virtual reality headset device, a simple film about endoscopy and nature film with high quality waterfall images and sounds in a 15 minute interval before the endoscope.
Category
Treatment - Other

2

Description

Control group: Receive routine care without any special intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid modarres hospital

Full name of responsible person

Tahmine Ghasimi

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17 Shahrivar Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Ali Mohammadpur

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Habib Shareinia

Position

Instructor at School of Nursing and Midwifery

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Ali Mohammadpur

Position

head of the University of Nursing and Midwifery Faculty

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

student at master nursing

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available