Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Street address

17 Shahrivar Ave

City

Kashmar

Province

Razavi Khorasan

Postal code

9671616669

Phone

+98 51 5522 7402

Email

ghasimi.t@gmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Ali Mohammadpur

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 5027

Email

info@gmu.ac.ir

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

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 5027

Email

shareinia.msn@gmail.com

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

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 5027

Email

amohammadpur@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
Tahmine Ghasimi

Position
student at master nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Edalat Ave

City
Kashmar

Province
Razavi Khorasan

Postal code
9671936686

Phone
+98 51 5523 6303

Email
ghasimi.t@gmu.ac.ir

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