

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing the effect of virtual reality and rhythmic breathing on patient's Situational anxiety, fear and physiological variables prior to upper gastrointestinal endoscopy

Protocol summary

Study aim

Comparison of the Effects of Virtual Reality and Rhythmic Breathing on Situational Anxiety, Fear, and Physiological Variables Before Upper Gastrointestinal Endoscopy

Design

Randomized clinical trial on 60 patients.

Settings and conduct

Eligible participants will be recruited from the endoscopy unit at Imam Sajjad Hospital (Ramsar) and randomly allocated to either the intervention group (virtual reality, VR) or the control group (rhythmic breathing). Following informed consent and completion of a demographic questionnaire, baseline physiological parameters (e.g., blood pressure, heart rate), anxiety (assessed using the Spielberger State-Trait Anxiety Inventory [STAI]), and fear (measured via a Visual Analog Scale [VAS]) will be recorded one hour before the endoscopic procedure. In the VR group, patients will undergo a 12-minute immersive session using a VR headset displaying nature scenes, religious sites, or tourist destinations, while the rhythmic breathing group will perform controlled breathing exercises (3-second nasal inhalation, 3-second breath-holding, 3-second oral exhalation) in a supine position with closed eyes, repeated at 5-minute intervals over 20 minutes. Both groups will undergo identical reassessment of physiological variables, anxiety, and fear levels 20 minutes post-intervention (20 minutes before endoscopy) to evaluate the comparative impact of each method on anxiety and fear reduction.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 and over, First experience of endoscopic examination of the gastrointestinal tract.
Exclusion criteria: visual and auditory impairment, History of anxiety and psychological problems

Intervention groups

Patients waiting for gastrointestinal endoscopy

Main outcome variables

Situational anxiety and fear

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250407065237N1**

Registration date: **2025-04-12, 1404/01/23**

Registration timing: **prospective**

Last update: **2025-04-12, 1404/01/23**

Update count: **0**

Registration date

2025-04-12, 1404/01/23

Registrant information

Name

Mahshad Hasansorodi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 11 5521 0828

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m.hasansarvari@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-30, 1404/02/10

Expected recruitment end date

2025-08-01, 1404/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of virtual reality and rhythmic breathing on patient's Situational anxiety, fear and physiological variables prior to upper gastrointestinal endoscopy

Public title

Effect of virtual reality and rhythmic breathing on patients prior to gastrointestinal endoscopy

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 and over Consent to participate in the research Awareness and orientation to time and place The first experience of endoscopic examination of the digestive system. ability to communicate verbally

Exclusion criteria:

Study participation reluctance Visual and auditory impairment History of anxiety and psychological problems Use of medications that affect anxiety

Age

From **18 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

Researchers will select participants in this study based on the inclusion criteria: Randomization will be conducted using a web-based tool, with 60 subjects independently randomized into 4 equally sized blocks. The generated sequences will be recorded using Randomizer software, and the assigned codes will be placed in opaque envelopes. Upon the enrollment of each new participant, the envelope will be opened to determine the corresponding group. The individual responsible for generating the randomization list will not participate in any other aspect of the study to prevent selection biases and ensure a uniform distribution of characteristics across both groups. This process aids in reducing the imbalance of confounding factors between the study groups and enhances the validity of the results.

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**

Health Research Institute, Babol University of Medical Sciences

Street address

Shahid Motahari Street - Enghelab Square - Imam Sajjad Hospital - Fatemeh Zahra (S) Nursing and Midwifery School- Ramsar- Mazandaran- Iran

City

Ramsar

Province

Mazandaran

Postal code

۴۶۹۱۷۱۴۱۴۱

Approval date

2025-01-22, 1403/11/03

Ethics committee reference number

IR.MUBABOL.REC.1403.142

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

Upper gastrointestinal disease

ICD-10 code

K92.2

ICD-10 code description

Gastrointestinal hemorrhage, unspecified

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

Situational anxiety

Timepoint

Before and after the intervention

Method of measurement

Spielberger's Anxiety Inventory

2**Description**

Fear

Timepoint

Before and after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Blood pressure

Timepoint

Before and after the intervention

Method of measurement

Pressure gauge device

2

Description

Heart rate

Timepoint

Before and after the intervention

Method of measurement

Pulse oximeter

3

Description

Respiratory rate

Timepoint

Before and after the intervention

Method of measurement

Mobile phone stopwatch

4

Description

Arterial blood oxygen saturation percentage

Timepoint

Before and after the intervention

Method of measurement

Pulse oximeter

Intervention groups

1

Description

The study protocol will proceed as follows: One day before endoscopy, the researcher will coordinate with the department head to obtain a list of scheduled patients, who will be contacted via phone and instructed to arrive 1.5 hours before the procedure. Interventions will be conducted in the endoscopy waiting rooms. Upon arrival, eligible participants will receive detailed explanations of the study's objectives and procedures, and written informed consent will be obtained. A demographic questionnaire will then be completed by participants. One hour before endoscopy, physiological parameters—including blood pressure (measured from the left arm using a standardized aneroid sphygmomanometer [ALPK2, Japan]), pulse rate, respiratory rate (counted over one full minute using a Samsung A53 smartphone chronometer), and arterial oxygen saturation (assessed via a pulse oximeter [Zenith Med C101A3, China] on the left index finger)—will be recorded in a seated position with the arm aligned at heart level. Anxiety and fear will be quantified using the Spielberger State-Trait Anxiety Inventory (STAI) and a Visual Analog Scale (VAS), respectively. Pre-intervention

preferences for VR content (e.g., religious sites, natural landscapes) will be surveyed. Participants allocated to the virtual reality (VR) group will undergo a 12-minute immersive session using a Shinecon SC-GI5 VR headset (China) with high-quality audiovisual environments (self-selected serene scenes) to divert attention from the procedure and induce relaxation through sensory immersion. Twenty minutes post-intervention, physiological variables, anxiety, and fear will be reassessed. For the rhythmic breathing group, participants will perform controlled breathing exercises (3-second nasal inhalation, 3-second breath-holding, 3-second oral exhalation) in a supine position with closed eyes, repeated at 5-minute intervals over 20 minutes, followed by identical post-intervention measurements. All assessments will be standardized to compare the efficacy of VR versus rhythmic breathing in reducing pre-endoscopy anxiety and fear.

Category

Prevention

2

Description

Participants in the rhythmic breathing group will be instructed to close their eyes, assume a supine position, and perform a controlled breathing technique: inhaling through the nose for 3 seconds (counted audibly as "1-3"), holding the breath for 3 seconds, and exhaling through the mouth for 3 seconds. Patients will be directed to focus solely on the inflow and outflow of air during the exercise. The rhythmic breathing protocol will consist of 1-minute sessions repeated every 5 minutes over a 20-minute period, with adherence to the taught method. Physiological parameters (blood pressure, pulse, respiratory rate, arterial oxygen saturation), anxiety (assessed via the Spielberger State-Trait Anxiety Inventory [STAI]), and fear (measured using a Visual Analog Scale [VAS]) will be evaluated at two timepoints: (1) one hour prior to endoscopy (baseline) and (2) 20 minutes post-intervention (20 minutes before the procedure), mirroring the assessment protocol of the virtual reality group to ensure comparability.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Sajjad Hospital, Ramsar

Full name of responsible person

Mohammad Hasan Nadimi

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Imam Sajjad Hospital- Shahid Motahari Street--

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Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

2

Recruitment center

Name of recruitment center
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Full name of responsible person
Nazerian Ebrahim
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Person responsible for general inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Mahshad Hasansorodi
Position
Master's degree student in nursing
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Jannat Alipour Zahra
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Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Pourhabib Ali

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

We can share all data on primary and secondary
outcomes after de-identifying individuals.

When the data will become available and for how long

Access period starts 3 months after results are
published.

To whom data/document is available

It will be available to researchers working in academic
and scientific institutions.

Under which criteria data/document could be used

Scientific and clinical use of data is permitted if
permission is obtained and intellectual and material
rights are preserved.

From where data/document is obtainable

Email address, phone numbers, postal address for
correspondence mahshad.hasansorodii@gmail.com -
0098 9118045925 zalipoor@gmail.com
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What processes are involved for a request to access data/document

The applicant should contact us through the
communication channels introduced. After reviewing
their request, if there is no conflict with the principles
and objectives of the research, the data will be made
available to them as soon as possible within a period of 7
days.

Comments