Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Iran (Islamic Republic of)

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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

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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
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Sponsors / Funding sources

1

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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
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
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Mahshad Hasansorodi
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Master's degree student in nursing
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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
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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