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Can pain and anxiety be reduced in cystoscopy?

Submission date 04/09/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 05/09/2025	**Overall study status** Completed	
Last Edited 05/09/2025	**Condition category** Urological and Genital Diseases	

Plain English summary of protocol

Background and study aims
Flexible cystoscopy is a routine outpatient procedure used to examine the bladder. Although it is generally safe, many patients feel anxious and experience discomfort during the procedure. This study is testing whether two simple, non-invasive methods, showing patients a short educational video before the procedure and using virtual reality (VR) distraction during the procedure, can make the experience less stressful and less painful.

Who can participate?
Adult patients who need flexible cystoscopy at Ümraniye Training and Research Hospital

What does the study involve?
Patients will be randomly assigned to one of four groups: (1) video only, (2) video + VR, (3) VR only, and (4) routine care without video or VR. The video explains the procedure in simple terms, while the VR headset shows calming 360° nature scenes.

The study will measure patients' long-term tendency to experience anxiety and their current state of anxiety using questionnaires before and immediately after the procedure. Pain intensity will be assessed during cystoscopy using a scale. All procedures will be performed by experienced urologists under local anaesthesia, and data will be collected by a second physician.

What are the possible benefits and risks of participating?
The results of this study will help determine whether video education and VR distraction are effective in reducing anxiety and pain during flexible cystoscopy, and may guide improvements in patient care.

No risks given at registration.

Where is the study run from?
Ümraniye Training and Research Hospital, Department of Urology.

When is the study starting and how long is it expected to run for?
October 2024 to January 2025

Who is funding the study?
Ümraniye Training and Research Hospital, Department of Urology. (no external funding)

Who is the main contact?
Dr Murat Beyatlı, muratbeyatli_90@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effects of pre-procedural video education and intra-procedural virtual reality on anxiety and pain during flexible cystoscopy: a randomized controlled trial

Acronym
VR-CYSTO

Study objectives

To evaluate whether pre-procedural video education and intra-procedural virtual reality distraction reduce anxiety and pain compared to standard care in patients undergoing flexible cystoscopy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/11/2024, Ümraniye Training and Research Hospital Ethics Committee (Elmalıkent Neighborhood Adem Yavuz Street No:1, Ümraniye/Istanbul, 34760, Türkiye; +90 (0216) 632 18 18 /11 64; not@available.com), ref: 370

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Procedural anxiety and pain in patients undergoing flexible cystoscopy

Interventions
Randomisation is 1:1:1:1 using computer-generated allocation.
Participants are randomised into four parallel arms:
1. Pre-procedural educational video + VR headset during cystoscopy;
2. Educational video only;
3. VR headset only;
4. Control group receiving standard care (no video, no VR).
The video lasts ~3 minutes and explains the cystoscopy procedure. The VR headset shows neutral, relaxing content during the procedure until completion (average 5–10 minutes).

Intervention Type
Behavioural

Primary outcome measure
1. Pain intensity measured using the Visual Analogue Scale (VAS, 0–10) during the cystoscopy procedure

2. State anxiety measured using the State-Trait Anxiety Inventory – State (STAI-S) at baseline (before cystoscopy) and immediately after the procedure

Secondary outcome measures
1. Trait anxiety measured using the State-Trait Anxiety Inventory – Trait (STAI-T) at baseline only, before the procedure.
2. Adverse events, defined as any complications or side effects observed during or after cystoscopy (e.g., dizziness, nausea, vasovagal symptoms), measured using medical records at one timepoint

Overall study start date
07/10/2024

Completion date
30/01/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Indication for flexible cystoscopy
3. Adequate cognitive function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Total final enrolment
240

Key exclusion criteria
1. Current use of anxiolytics, antidepressants, or opioids
2. Prior history of cystoscopy
3. Significant cognitive or psychiatric disorders
4. Severe hearing/visual impairment preventing video or VR use
5. Active urinary tract infection or chronic bladder pain
6. History of severe allergic reaction to local anesthetics
7. Pregnancy

Date of first enrolment
08/11/2024

Date of final enrolment
30/01/2025

Locations

Countries of recruitment
Türkiye

Study participating centre
Ümraniye Training and Research Hospital, Department of Urology
Elmalıkent Mahallesi Adem Yavuz Cad. No:1 Ümraniye / İstanbul
Istanbul
Türkiye
34764

Sponsor information

Organisation
Ümraniye Training and Research Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
https://umraniyeah.saglik.gov.tr/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ümraniye Training and Research Hospital

Results and Publications

Publication and dissemination plan
The findings of this trial will be submitted for publication in a peer-reviewed scientific journal within one year of study completion and may also be presented at national and international urology conferences

Intention to publish date
20/09/2025

Individual participant data (IPD) sharing plan
De-identified or anonymised datasets of individual participant data (IPD) will be made available from the corresponding author (Murat Beyatlı, muratbeyatli_90@hotmail.com) on reasonable request after publication of the study results. Data will be shared for academic purposes only, in anonymised form, without any information that could identify individual participants.

IPD sharing plan summary
Available on request