

# Can pain and anxiety be reduced in cystoscopy?

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<b>Registration date</b> 05/09/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/09/2025	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## 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

### Contact name

Dr Murat Beyatlı

### ORCID ID

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Quality of life, Efficacy

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **Completion date**

30/01/2025

## **Eligibility**

**Key inclusion criteria**

1. Age  $\geq 18$  years
2. Indication for flexible cystoscopy
3. Adequate cognitive function

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

## Funder(s)

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Ümraniye Training and Research Hospital

## Results and Publications

**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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes