STUDY COVER PAGE

Official Study Title: Effect of Video-Based Information on Anxiety, Depression, and Stress Before Cystoscopy: A Prospective Randomized Controlled Trial

Brief Title: Video Education to Reduce Anxiety and Depression Before Cystoscopy (VIDEOCYS)

Unique Protocol ID: IRB0242IKCU

NCT Number: Pending Assignment

Date of Document: May 15, 2025

Principal Investigator:

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Izmir Katip Celebi University

INFORMED CONSENT FORM FOR VOLUNTEERS

[PLEASE READ CAREFULLY!]

Before agreeing to participate in this study,

it is important that you understand the purpose of the research. Your decision to participate should be made voluntarily after reviewing this information.

1. INFORMATION ABOUT THE STUDY

Title of the Study:
Investigation of Factors Affecting Anxiety and Depression in Patients Undergoing Cystoscopy

Description of the Study:
This study aims to evaluate psychological conditions such as anxiety, stress, and depression in patients before undergoing cystoscopy (an endoscopic procedure performed to visualize the inside of the bladder). As part of the study, you will be asked to complete several brief psychological assessment forms (scales) at two different time points: before and after the procedure.

Purpose of the Study:
The purpose of this research is to identify factors affecting anxiety and depression levels in

patients prior to cystoscopy. The findings from this study aim to help provide better support for patients preparing for similar procedures in the future.

Estimated Duration of Participation:
Your participation in this study will last for only one day. You will complete brief assessments before and after the procedure, which will take approximately 10315 minutes in total.

Expected Number of Volunteers to Participate:
It is planned that a total of 180 volunteer patients will participate in this study.

Procedures and Interventions to Be Followed During the Study:
Participants will be asked to complete psychological assessment forms to evaluate levels of anxiety, stress, and depression before and after the procedure. All assessments will be conducted verbally or in writing and will not involve any painful or harmful procedures.

Procedures:

- Completion of anxiety and depression scales before the procedure
- Undergoing the cystoscopy procedure
- Completion of the same scales again after the procedure

2. POTENTIAL BENEFITS OF PARTICIPATING IN THE STUDY

Participation in this study may not provide any direct health benefits to you. However, the information obtained may contribute to the development of methods to help patients experience less anxiety prior to procedures such as cystoscopy. Therefore, this study may provide important benefits for patients undergoing similar procedures in the future.

3. POTENTIAL RISKS AND DISCOMFORTS DURING PARTICIPATION

This study will not involve blood sampling, medication administration, or any surgical intervention. The procedures will solely consist of completing psychological assessment questionnaires. Some participants may experience mild, short-term discomfort, boredom, or emotional reactions while completing these scales. These feelings are temporary, and you have the right to withdraw from the study at any time without any consequences.

All assessments will be conducted in a quiet and secure environment with attention to patient comfort.

4. EXPECTED MEDICAL BENEFITS FOR VOLUNTEERS

Participation in this research does not serve as a form of treatment or diagnosis. However, the information obtained from this study aims to contribute to the development of methods that will

help patients undergoing similar procedures to be better psychologically prepared and to reduce their anxiety levels prior to the procedure. In this regard, the research may provide indirect benefits to the healthcare system and to other patients.

5. PREGNANCY

Individuals who are pregnant will not be included in this study. It is considered that hormonal and emotional changes during pregnancy may affect the results of the psychological assessments, and the research scales used in this study may not be appropriate for this specific group.

Participants will be informed about the exclusion of pregnancy prior to participation, and if necessary, will be excluded from the study.

6. INFORMATION ABOUT ALTERNATIVE PROCEDURES OR TREATMENTS

This study does not involve any therapeutic procedures or interventions. If you choose not to participate in this study, none of your medical rights will be restricted, and your scheduled cystoscopy procedure and other routine medical services will continue as planned.

7. CONDITIONS FOR WITHDRAWAL FROM THE STUDY

If you refuse to complete the questionnaires during the study, do not comply with the study procedures, or wish to withdraw voluntarily, you may leave the study at any time without providing any justification. Additionally, the study investigator may terminate your participation without your consent if there is a medical or ethical necessity to do so.

8. COSTS ASSOCIATED WITH THE STUDY

This study does not involve any medical procedures, tests, or treatments for participants. The procedures consist solely of completing psychological assessment forms. No fees will be charged to participants, and no payments will be requested from social security institutions or any public/private organizations. No additional costs related to the study are anticipated, and any necessary stationery or similar expenses will be covered by the researchers.

9. WILL ANY PAYMENT BE MADE FOR PARTICIPATION IN THE STUDY?

Participation in this study is entirely voluntary, and no payment will be provided for participation. Due to the nature of the study, there are no anticipated costs related to transportation, examinations, or treatments. Therefore, there is no plan to provide payments for travel or visits.

Signature/Stamp:
Name and Surname of Responsible Investigator

10. CONTACT INFORMATION FOR ISSUES THAT MAY ARISE DURING THE STUDY

If you need further information about the study, have questions, or experience any discomfort or unexpected situations related to the study, you may contact the responsible investigator using the information below:

Enis Mert Yorulmaz, MD.
Phone 1: +90 506 497 03 87
Phone 2: +90 507 686 53 69

11. COMPENSATION FOR DAMAGES

As this study does not involve any medical interventions, medication administration, or invasive procedures, no physical harm related to the study is anticipated. However, if you experience any psychological discomfort or encounter any adverse situations during your participation, necessary medical support will be provided by the responsible investigator.

The procedures in this study are limited to completing psychological assessment forms. No financial burden is anticipated during the study, and as your participation is voluntary, no additional costs will be incurred by you.

12. VOLUNTARY PARTICIPATION, RIGHT TO REFUSE, WITHDRAWAL FROM THE STUDY, AND REMOVAL FROM THE STUDY

a. I voluntarily agree to participate in this study without any pressure or coercion.

b. I have been informed that I have the right to refuse to participate in the study.

c. I understand that I can withdraw from this study at any time without providing any justification, provided that I inform the responsible investigator/physician. I am aware that refusing to participate or withdrawing from the study will not place me under any obligation and will not affect my current or future medical care in any way.

d. I understand that the investigator/physician conducting the study or the sponsoring organization may remove me from the study without my consent if I fail to comply with the study requirements or if it is necessary to improve the quality of the medical care I am receiving.

Signature/Stamp:
Name and Surname of Responsible Investigator

13. CONFIDENTIALITY

All information obtained during this study will be kept confidential. Your identity, responses, and personal health information will not be shared with any institution, company, or third parties. The data obtained from this study will be used solely for scientific purposes and may be presented at academic meetings or published in scientific journals when necessary. In such cases, your identity will not be disclosed, and the data will be used in an anonymized form. Research records may be reviewed, if necessary, by ethics committees, regulatory authorities, or individuals authorized for scientific review, in accordance with confidentiality principles. The protection of your identity and personal information will be ensured at the highest level throughout your voluntary participation in this study.

14. CONSENT TO PARTICIPATE IN THE STUDY

I have read, or have had read to me, this Informed Consent Form, which contains the information that must be provided to the volunteer before participation in the study, in my native language. The content and meaning of this information have been explained to me both in writing and verbally. I have been given the opportunity to ask any questions I had in mind, and I have received satisfactory answers to my questions.

I understand that if I choose not to participate in the study or if I decide to withdraw after participating, I will not forfeit any of my legal rights. Under these conditions, I voluntarily agree to participate in this study without any pressure or coercion.

A signed copy of this form has been provided to me.

Name and Surname of Volunteer:
Age and Gender:
Signature:
Address (and phone and/or fax number if available):
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Date:

For individuals under guardianship or custody:
Name and Surname of Parent or Legal Guardian:
Signature:
Address (and phone and/or fax number if available):
.....
.....

Date:

Signature/Stamp:
Name and Surname of Responsible Investigator

Name and Surname of Researcher/Physician Providing Explanations:
Signature:
Date:

Name and Surname of Institutional Witness Present Throughout the Consent Process:
Signature:
Position:
Date:

Signature/Stamp:
Name and Surname of Responsible Investigator