Official Title:

Evaluation the Effects of Dynamic Video Education Compared to Static Images and Verbal Information on Pain Perception and Anxiety in Patients Undergoing Transrectal Ultrasound-guided Prostate Biopsy (TRUS-Bx)

National Ethics Committee Number: AEŞH-EK1-2023-100

Date: 10/12/2023

INFORMED CONSENT FORM (ICF)

STUDY TITLE:

*"***A Prospective Comparative Study of the Effect of Video Education on Pain and Anxiety in Patients Undergoing TRUS-Guided Prostate Biopsy***"*

You are being invited to participate in a research study described below. Your participation is entirely voluntary. Before deciding whether to participate, it is important that you understand why the research is being conducted, how your information will be used, what the study involves, and any potential benefits or risks. Please take your time to read the following information carefully. If you decide to participate, please sign the Informed Consent Form. You are free to withdraw at any time. There will be no financial compensation or material request for your participation in this study.

STUDY TOPIC AND PURPOSE:

The widespread use of PSA (Prostate-Specific Antigen) has facilitated early detection of prostate cancer. Patients with elevated PSA and abnormal digital rectal examination findings are advised to undergo biopsy. Transrectal ultrasound-guided prostate biopsy is the standard diagnostic procedure for prostate cancer. As the frequency of PSA testing increases, so does the number of biopsies performed.

These procedures have been reported to cause anxiety, pain, and stress in male patients. Nowadays, it is common for patients to seek information online. Watching videos of medical procedures on digital platforms before surgery is widespread. This study aims to evaluate the anxiety and stress levels of patients before and after the TRUS-BX procedure based on their exposure to related videos.

STUDY PROCEDURES:

If an increase in anxiety-stress scores is observed as a result of the study, it may indicate the need for additional measures to better inform patients pre-procedure. Videos may be adjusted to reduce stress and improve patient comfort during biopsy. However, some patients might delay or avoid necessary diagnostic and treatment procedures due to anxiety triggered by these videos. This study may also guide the appropriate regulation of visual content on digital platforms.

The study compares pre- and post-procedural anxiety scores and visual analog scale (VAS) pain scores. All patients are informed in the clinic that a TRUS-BX procedure will be performed due to elevated PSA. The procedure is explained to each patient individually in a comprehensible manner. The study design was reviewed and finalized with the contributions of Dr. Ayşe Gökçen Gündoğmuş from the Psychiatry Department of Ankara Etlik City Hospital.

Control Group:

- After standard verbal information, patients complete the VAS test.
- No visual materials are shown.
- STAI-II (Trait Anxiety) and STAI-I (State Anxiety) are administered pre-procedure.
- After biopsy, VAS and STAI-I are repeated.

Video Group:

- After standard verbal information, patients complete the VAS test.
- Procedure-related videos are found and watched with the patient via digital video platforms.
- STAI-II and STAI-I are administered pre-procedure.
- After biopsy, VAS and STAI-I are repeated.

Image Group:

- After standard verbal information, patients complete the VAS test.
- Drawings or illustrated images (from books) related to the procedure are shown.
- STAI-II and STAI-I are administered pre-procedure.
- After biopsy, VAS and STAI-I are repeated.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If an increase in anxiety-stress scores is detected, new measures may be taken to improve patient preparation. Adjusting videos to reduce stress may help decrease anxiety. It may also enhance the comfort level of patients during the biopsy procedure.

WHAT IS THE COST OF PARTICIPATION?

There is no cost to participate in the study. No financial compensation will be provided.

SHOULD I PARTICIPATE IN THIS STUDY?

Participation is entirely up to you. Even if you sign this form now, you may withdraw from the study at any time without giving any reason. If you choose not to participate or decide to withdraw, your physician will continue to provide the most appropriate treatment for you. Similarly, if the investigator believes continuing in the study is not in your best interest, you may be withdrawn, and the best alternative treatment will be offered.

HOW WILL MY PERSONAL INFORMATION BE USED?

Your doctor will use your personal information to conduct the study and perform statistical analysis. However, your identity will be kept confidential. If necessary, ethics committees or official authorities may review your information. You have the right to request your personal study results. Study outcomes may be published in medical literature, but your identity will not be revealed.

CONTACT INFORMATION FOR QUESTIONS AND CONCERNS:

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CONSENT TO PARTICIPATE IN THE STUDY

I have discussed the information above with the investigator in detail and all of my questions have been answered. I have read and understood this informed consent form. I voluntarily agree to participate in this study and sign this consent of my own free will. This consent does not invalidate any applicable laws or regulations. A copy of this form, including important notes for me to consider during the study, has been provided to me.

Volunteer Full Name:
Date and Signature:
Phone:

(If applicable) Legal Guardian Full Name:
Date and Signature:
Phone:

Witness Full Name:
Date and Signature:
Phone:

Investigator Full Name:
Date and Signature:
Phone: