OFFICIAL TITLE:

Effects of Stress Ball Use and Music Listening on Anxiety, Stress, and Pain in Platelet Apheresis Donors: A Randomized Controlled Trial

NCT NUMBER:-

DOCUMENT TITLE:

Informed consent form-Stress ball group

DOCUMENT DATE:

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THE EFFECT OF STRESS BALL and MUSIC ON ANXIETY, STRESS, AND PAIN LEVELS DURING PLATELET APHERESIS DONATION: RANDOMIZED CONTROLLED TRIAL

INFORMED CONSENT FORM
Stress Ball Group

Principal Investigator: D** U**

Purpose of the Study:
This study aims to investigate the effects of routine care provided according to the standard protocol, stress ball exercises as a distraction and attention-diverting method, and music listening on anxiety, stress, and pain levels in platelet apheresis donors. The findings of this study are expected to provide evidence regarding the effects of stress ball use and music listening on anxiety, stress, and pain during platelet apheresis donation.

Study Procedure:
This study will be conducted at the Tekirdağ Namık Kemal University Hospital Blood Transfusion Center with voluntary donors who wish to donate platelets by apheresis, are aged 18 years or older but under 55 years, and have no communication difficulties.

If you voluntarily agree to participate, Medical Laboratory Technician Fatma ÖZCANLI and Specialist Nurse Dilek URTEKİN will ask you to complete the Donor Information Form, Distress Thermometer, Beck Anxiety Inventory, and Visual Analog Scale for Pain as pre-test assessments 5 minutes before the platelet apheresis procedure. Your vital signs will be recorded on the Donor Monitoring Chart.

After completing these data collection forms, a stress ball will be placed in the palm of one of your hands. You will be asked to squeeze the stress ball as often as you wish, for a total duration of approximately 30 minutes during the platelet apheresis procedure.

Five minutes after the donation is completed, you will again complete the Distress Thermometer, Beck Anxiety Inventory, and Visual Analog Scale for Pain as post-test assessments. Your vital signs will again be recorded on the Donor Monitoring Chart. Completing all data collection tools will take approximately 10–15 minutes of your time.

No fees will be requested from you or your social security institution for participation in this research.

The research protocol has been reviewed and approved by the Ethics Committee of Tekirdağ Namık Kemal University Faculty of Medicine. The ethical principles outlined in the Declaration of Helsinki will be strictly followed. A copy of this form will be provided to you for your records.

Alternative Treatments or Interventions:
No alternative treatments or interventions will be applied due to this study.

Potential Risks During the Study:
There are no risks associated with your participation in this study.

Possible Side Effects of Study Medication:
No medication will be administered as part of this study.

Contact Person Available 24 Hours During the Study:
Specialist Nurse D** U**
Mobile Phone: 05** ** ** 11

Your participation in this study will be kept completely confidential. The only person who will have information about your participation is your doctor. Clinical information will be kept confidential to the same extent as the information you provide to your doctor or nurse. However, inspectors from authorized institutions may be required to review your study records to ensure that the research is conducted in accordance with applicable laws and health authority regulations. The information in your records will be used solely for the purposes of this study and related publications. Your identity will be protected at all times. Under no circumstances will your identity be used for other purposes or disclosed to third parties. You will not be charged for examinations or other procedures related to the study.

I have read and listened to the information that must be provided to the volunteer before the start of the study. I have read all explanations in the Informed Consent Form. Written and verbal explanations regarding the study, including its purpose and procedures, were provided to me by the physician named below. I have asked all questions I had to the investigator and fully understand all written and verbal explanations provided. I have been given sufficient time to decide whether I want to participate in the study. I understand that I am participating voluntarily, that I may withdraw from the study at any time with or without justification, and that I may be removed from the study by the investigator regardless of my wishes.
I agree to participate in this study voluntarily and without any pressure or coercion. I authorize the investigator to review, transfer, and process my medical information, and I accept the invitation to participate in this study freely and voluntarily.

Volunteer's Name / Surname / Signature / Date: _____

Name / Surname of Person Providing Explanations / Signature / Date:
_____

If Applicable, Witness to Consent Name / Surname / Signature / Date:
_____
I
f Applicable, Legal Representative Name / Surname / Signature / Date:
_____