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:

Study Protocol

DOCUMENT DATE:

January 31, 2023

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

1. Introduction

Platelet apheresis transfusion can be used for therapeutic or prophylactic purposes, primarily in oncology and hematology patients (1). Platelet apheresis donors may experience anxiety, stress, and pain due to the need for a wide-lumen vascular access site to ensure adequate blood flow, the complexity of the devices used during the procedure, and the need to keep a needle in the donor's arm for an average of 1 hour. There are numerous approaches, including pharmacological and non-pharmacological methods, to reduce these negative feelings (2). The use of non-pharmacological methods such as listening to music, squeezing a stress ball, watching a movie, using virtual reality glasses, daydreaming, and smelling lavender during invasive procedures has been shown to reduce anxiety, stress, and pain symptoms in individuals (3).

During invasive procedures, stress balls, which are inexpensive and accessible, have been observed to be used as a distraction and attention-grabbing method to reduce anxiety, stress, and pain (4,5,5). Listening to music is another non-pharmacological method that can alleviate anxiety, stress, and pain during invasive procedures. Listening to music before and during invasive procedures has been found to reduce systolic blood pressure, heart rate, and anxiety levels (7,8).

A review of the literature revealed no studies using squeeze ball therapy targeting the sense of touch and music listening targeting the sense of hearing to relieve anxiety, stress, and pain during platelet apheresis donation (PAD). In this context, this study aims to investigate the effects of applying a stress ball, a distraction-attention method, and listening to music, which targets the sense of hearing, on anxiety, stress, and pain levels in platelet apheresis donors, in addition to routine care. It is believed that the data obtained at the end of the study will provide evidence of the effect of stress balls and music listening used during platelet apheresis donation on anxiety, stress, and pain.

Research Hypotheses

H1: There is a significant difference in anxiety levels between donors who receive routine care, use stress balls, and listen to music during PAD.

H2: There is a significant difference in stress levels among donors who receive routine care, use stress balls, and listen to music during PAD.

H3: There is a significant difference in pain levels among donors who receive routine care, use stress balls, and listen to music during PAD.

2. Materials And Methods

Research Purpose and Design

This study was a single-center, prospective, randomized controlled trial designed to investigate the effects of using stress balls, a distraction-attention method, and listening to music on anxiety, stress, and pain levels in PAD, in addition to routine care.

Research Population, Sample

When determining the sample size, the effect size was calculated using results similar to a master's thesis (9). The sample size for the study was calculated using the G-power (v3.1.9.7) program with “effect size = 0.30, alpha = 0.05, power = 0.85, number of groups = 3, and number of measurements = 2” using ANOVA: Fixed effects, omnibus, one-way. The specified calculation yielded a minimum sample size of 93 donors, with 31 donors per group. 14 individuals who declined to participate, 15 who did not meet the inclusion criteria were excluded from the study. Taking all these losses into account, the study was completed with a total of 102 individuals, 34 in each study group.

The study included participants aged ≥18 and ≤55 who could read Turkish, had no physical limitations preventing them from squeezing a stress ball, had no psychiatric disorders, vision, hearing, or perception problems, met the platelet apheresis donation criteria according to the institutional protocol, were first-time platelet apheresis donors, voluntarily wished to donate platelets by apheresis, and voluntarily agreed to participate in the study.

Donors who withdrew from PAD, wished to leave the study, developed a reaction during donation, or were unable to complete the procedure due to insufficient blood flow through the catheter were not included in the study.

Ensuring Randomization

Platelet apheresis donors were randomly assigned to groups using a stress ball, music listening, and a random number table—a simple random sampling method—to minimize selection bias.

Data Collection Tools

Data were collected by researchers at a university hospital's blood transfusion center between August 1, 2024, and August 1, 2025. Donors were asked to complete questionnaire forms before and after PAD, a process that took approximately 10-15 minutes.

Donor Information Form (DIF): The researchers created the Donor Information Form, which contains a total of 14 questions. The form consists of two sections: socio-demographic characteristics and donor parameters. The first section contains questions about the donors' socio-demographic characteristics (age, gender, education level, occupation, family type, place of residence, and tobacco/alcohol use). The second section contains questions about donor characteristics (blood type information, previous blood donation, and degree of kinship with the recipient).

Beck Anxiety Scale (BAS): Measures the frequency of anxiety symptoms experienced by the individual. Beck and colleagues developed it and, it is a 21-item Likert-type self-assessment scale (10). The Turkish validity and reliability study was conducted by Ulusoy and colleagues (11). The sum of the scores is evaluated as follows: 0-7: Minimal anxiety, 8-15: Mild anxiety, 16-25: Moderate anxiety, 26-63: Severe anxiety. The total score is used in the evaluation of the scale, and an increase in the score indicates an increase in the level of anxiety (10).

Distress Thermometer (DT): Roth and colleagues developed it in 1998 to measure and evaluate the psychosocial distress experienced by cancer patients (12). Its validity and reliability in Turkish were established by Özalp and colleagues (13). "0" represents no distress, "10" indicates the highest level of distress. The cutoff point is 4 points, and it is recommended that patients with a distress level of 4 points or higher should receive professional support (12).

Visual Analog Scale (VAS): The Visual Pain Scale is a safe, valid, and easy-to-use tool for measuring pain repeatedly (14). Its validity and reliability in Turkish were established by Yaray and colleagues (15). "0" on the vertical or horizontal scale denotes no pain, while "10" signifies unbearable pain (14,15).

Donor Monitoring Chart: The form prepared by the researchers was used to record vital signs such as temperature, heart rate, blood pressure, respiratory rate, and oxygen saturation before and after the procedure.

The Approach Followed in Data Collection and Evaluation

Pre-Implementation Phase

Prior to commencing the research, a pre-implementation was conducted on a sample representing 10% of the individuals included in the sample scope. This exercise was done to test the clarity and usability of the scales and forms to be used as data collection tools and to evaluate the applicability of using a stress ball and listening to music. Based on the results of the pre-implementation, adjustments were made to the research content, forms, stress ball application, and music listening session, leading to the final form being determined. The data obtained in the pre-implementation phase were not included in the research.

Implementation Phase

The researchers informed donors who met the inclusion criteria about the study's purpose, design, and method and obtained their consent using the Informed Consent Form prepared separately for each group.

Stress Ball Group

Ten minutes before PAD, DIF, BAS, DT, and VAS were completed as pre-tests during a face-to-face interview, and vital signs were recorded on the Donor Monitoring Chart (DMC). When the PAD procedure began, a stress ball was placed in the palm of one hand. Donors were instructed to squeeze the ball as often as they wished for a total of 30 minutes during the procedure. Five minutes after the donation was completed, the BAS, DT, and VAS were filled out as final tests. Vital signs were recorded on the DMC, and the study was concluded.

Music Listening Group

Ten minutes before PAD, DIF, BAS, DT, and VAS were completed as pre-tests during a face-to-face interview, and vital signs were recorded on the DMC. After the PAD began, donors listened to classical Turkish music modes played through the center's speaker system for 30 minutes. Five minutes after the donation was completed, the BAS, DT, and VAS were filled out as a final test, vital signs were recorded, and the study was concluded.

Control group

Ten minutes before PAD, the DIF, BAS, DT, and VAS were completed as pre-tests during a face-to-face interview, and vital signs were recorded on the DMC. Donors in the control group underwent no intervention during platelet apheresis donation and continued their routine treatment and care. Five minutes after the procedure was completed, the BAS, DT, and VAS were filled out as post-tests. Vital signs were recorded, and the study was concluded.

Ethical Aspects of the Study

Local ethical committee approval (research protocol number: 2023.03.01.03) was obtained to conduct the study. Written permission was obtained from the center where the researcher would be working. The researchers' identity information and data obtained from the study were kept confidential.

Statistical Analysis and Evaluation of Data

The data obtained in the study were statistically analyzed using the SPSS v29.0 (IBM) software package. Chi-square analyses were conducted for the individual characteristics of the participants, one-way ANOVA was used for the means of vital signs, and both one-way ANOVA and Kruskal-Wallis tests were performed for anxiety, stress, and pain levels. We conducted chi-square analyses for anxiety, stress, and pain levels, one-way ANOVA and Kruskal-Wallis for smoking and alcohol use, t-tests for dependent groups, one-way ANOVA for vital signs, Kruskal-Wallis for anxiety, stress, and pain levels, t-tests for dependent groups, and one-way ANOVA for Beck Anxiety Scale scores. Data were evaluated at a 95% confidence interval and a $p<0.05$ statistical significance level.