INFORMED CONSENT FORM

Official Title: Determining the Effect of Music on Pain, Anxiety and Vital Signs in Cancer Patients Treated in Palliative Care Centers: A Quasi-Experimental Study

Unique Protocol ID: KMU-SHMYO-GK-01

NCT Number: ……..

Document Date: November 1, 2022

Principal Investigator:

Gülsüm Kehribar, PhD

Karamanoğlu Mehmetbey University

Study Sites:

- Yozgat City Hospital Palliative Care Center

- Karaman Training and Research Hospital Palliative Care Center

Ethics Committee Information:

Committee Name: Yozgat Bozok University Invasive (Non-Interventional) Clinical Research Ethics Committee

Approval Number: 2021.01-06

Approval Date: January 2021

INFORMED CONSENT FOR RESEARCH PARTICIPATION

Study Title: The Effect of Music on Pain, Anxiety and Vital Signs in Cancer Patients Receiving Palliative Care

You are being invited to participate in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

1. PURPOSE OF THE STUDY

This research aims to determine the effect of music on pain, anxiety, and vital signs in cancer patients receiving palliative care treatment.

2. STUDY PROCEDURES

If you agree to participate in this study, you will be asked to:

- Complete a demographic information form (age, gender, education, diagnosis, etc.)

- Complete questionnaires about your current pain level using the Visual Analog Scale (VAS) - a 10 cm line where you mark your pain from 0 (no pain) to 10 (worst pain)

- Complete the State-Trait Anxiety Inventory to assess your anxiety levels

- Allow measurement of your vital signs including:

  * Blood pressure

  * Pulse rate

  * Respiratory rate

  * Body temperature

  * Oxygen saturation (SpO2)

You will be randomly assigned to one of two groups:

INTERVENTION GROUP:

- You will listen to relaxing instrumental Turkish music (in Hicaz and Buselik maqams) for 30 minutes

- Music will be played through headphones using an MP3 player

- You will rest comfortably in bed while listening

- The session will occur between 10:00 AM and 5:00 PM after your morning pain medication

- All measurements will be repeated immediately after the music session

CONTROL GROUP:

- You will rest quietly in bed for 30 minutes without any activity

- The rest period will occur at the same time as the intervention group

- All measurements will be repeated immediately after the rest period

The total time required is approximately 60 minutes for one session.

3. RISKS AND DISCOMFORTS

The risks of this study are minimal:

- You may experience minor temporary discomfort from blood pressure measurement (arm cuff pressure)

- There are no known risks from listening to music

- If you experience any discomfort during the study, you may stop at any time

4. BENEFITS

Direct benefits to you:

- You may experience reduced pain and anxiety from the music intervention

- You may experience relaxation and improved mood

Benefits to others:

- The information from this study will help improve care for future palliative care patients

- This research will contribute to understanding non-pharmacological pain and anxiety management methods

5. CONFIDENTIALITY

- All information collected will be kept strictly confidential

- Your name will not appear in any reports, publications, or presentations

- You will be assigned a code number for identification

- Data will be stored in a locked cabinet and password-protected computer

- Only the research team will have access to the data

- Study records may be reviewed by the ethics committee

- All data will be retained for [X] years after study completion, then securely destroyed

6. VOLUNTARY PARTICIPATION AND WITHDRAWAL

- Your participation is completely voluntary

- You may refuse to participate without giving a reason

- You may withdraw from the study at any time without penalty

- Your decision to participate or not will NOT affect:

  * Your medical care

  * Your relationship with your healthcare providers

  * Your treatment at this hospital

- If you withdraw, data collected up to that point may still be used

7. COSTS AND COMPENSATION

- There are no costs to you for participating in this study

- You will not receive any payment for participating

- All study materials (MP3 player, headphones, music) will be provided

8. NEW INFORMATION

If new information becomes available that may affect your willingness to participate, you will be informed promptly.

9. QUESTIONS AND CONTACTS

If you have questions about this study, please contact:

Principal Investigator:

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If you have questions about your rights as a research participant,

please contact:

Karamanoğlu Mehmetbey University Clinical Research Ethics Committee

Phone: 05444104045

Email: glsm8585@gmail.com

10. STATEMENT OF CONSENT

I have read this consent form (or it has been read to me). I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I understand that my participation is voluntary and that I may withdraw at any time without penalty. I understand that I will receive a copy of this consent form. I voluntarily agree to participate in this research study.

_____ _____

Participant's Name (Print) Date

_____ _____

Participant's Signature Time

_____ _____

Person Obtaining Consent (Print) Date

_____ _____

Person Obtaining Consent Signature Time

_____ _____

Witness Name (Print) (if applicable) Date

_____ _____

Witness Signature (if applicable) Time