ALBERT EINSTEIN
INSTITUTO ISRAELITA DE ENSINO E PESQUISA

(Israeli Institute of Teaching and Research)

RESEARCH PROTOCOL

Evaluation of minimalist music and birdsongs in the anxiety of nursing professionals in Oncology.
Prof. Dr. Eliseth Ribeiro Leão.

Free and Informed Consent Form
Participants aged ≥ 18 years

Advisor: Prof. Dra. Eliseth Ribeiro Leao
Researcher: Fernanda Heleno Migueis Abrahão

Introduction

You are being invited to voluntarily participate of a study entitled "Evaluation of the minimalist music and birdsongs in the anxiety of nursing professionals in Oncology". For you to decide to take part thereof, you will need to know what your participation is about, as well as the possibilities of risks and benefits and confirm your participation through the signature of this free and informed consent form.

If you have any question, during or after reading this form, please feel free to enter in contact with the researcher in charge for the conduction of the study or with any professional that participates of the study who may clarify your questions.

The decision to take part of the study is voluntary and you can refuse to participate or withdraw from the study at any time with no type of consequence whatsoever for your treatment/professional relationship with the institution. The purpose of this research is to evaluate a type of musical intervention as a resource of relief of anxiety in professionals working in Oncology.

Procedures performed in this protocol

In this study, the participants will be allocated in three groups: a) control group (without intervention); b) intervention group with minimalist music and c) intervention group with minimalist music and birdsongs. The randomization process will be performed by the software Randomizer®. The interventions will be carried out individually right before and right after each

intervention, an anxiety evaluation instrument, in the format of a 6-question questionnaire will be applied. The intervention and application of the questionnaire last 15 minutes. The participants will have access to the results of the research, once the study is finished.

Duties of the participant

For the realization of this study, it is important that you are present during the 15 minutes of the intervention and respond the questionnaire (comprised by 6 questions) before and after the intervention. In case you are part of the control group, the questionnaire will be applied twice, with a 15-minute interval.

Risks and inconveniences

This study presents minimum risks. With the purpose to avoid the risk of breach of secrecy and confidentiality, the main investigator of this study undertakes to not share any information or reaction of the participant during the intervention performed and treat the data anonymously. Additionally, there is a risk of discomfort by the participant, and it is ensured that he/she can give up at any time of the research.

Benefit of the Study

There is a possibility of direct benefit to the participants to the extent that, if the intervention shows to be effective, it can generate a relief of anxiety and/or feeling of wellbeing. Additionally, there is an indirect benefit to the extent that, if the intervention shows to be effective, other persons can benefit from the reproduction of this work.

Rights of the Participant

Your participation is voluntary, and you can withdraw your consent or even discontinue your participation at any time, if you wish so, with no penalty and/or loss whatsoever. There will not be any cost to you arising from this study, considering that the study will be performed during a period that you will be at the hospital, that is, there is no transportation cost, for example. Additionally, there is no type of compensation for your participation.

By signing this form, you do not give up any legal right, including the right to seek indemnification in case of harm resulting from your participation.
If you are interested, you may request, at any time, information on the results of the tests performed in this study.

Harms

If an injury or any harm occurs as a result of your participation in this research, full assistance will be available with no cost to you, for the time that may be necessary.

Confidentiality

The study team will have access to your data; however, your anonymity is guaranteed and possible scientific publications resulting from this study will not identify you in any circumstance as a participant. The data obtained will be treated under strict confidentiality conditions.

Ethics

This study was approved by the Committee of Ethics in Research (CEP), a group of people that care for the protection of the participants of the research and evaluate the studies involving human beings in our institution. For any questions, ethical and/or related to rights of the research participants, get in contact with the Committee of Ethics in Research of Hospital Albert Einstein by the telephone (11) 2151-3729, or by the e-mail cep@einstein.be. The Committee works from Monday to Friday, from 7 AM to 5 PM, and is located at the Albert Einstein Education and Research Center – Campus Cecilia and Abram Szajman. Rua Comendador Elias Jafet, 755. Morumbi – SP, Postal Code: 05653-000,
Piso L4 – Suite 407-F/407-G. For any question related to the study, please feel free to get in contact with the people in charge of the study, Fernanda Abrahão, by the telephone (11) 992987170 or Eliseth Leão, by the telephone (11) 21511032.
Complaints, compliments and suggestions can be forwarded to the Customer Service System (SAC) by the telephone (11) 2151-0222 or the form identified as "talk to us" [*fale conosco*], available in the page of clinical research, or personally.

Consent Signatures

I was informed about all details related to the study that I participated. I will receive a signed, dated and initialized page of this Free and Informed Consent Form, being the other signed, dated and initialized copy remaining with the researcher.

_____

Research Participant's Full Name

_____ Date: ____/____/____

Research Participant's Signature

_____

Researcher in Charge Full and Legible Name

_____ Date: ____/____/____

Researcher in Charge Signature