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**Impact of Yoga and Gentle Massage Practices on Symptom Management in Patients
Undergoing Hematopoietic Stem Cell Transplantation at the Hospital Israelita Albert Einstein**

São Paulo

2023

Informed Consent Form (ICF)

Impact of Yoga and Gentle Massage Practices on Symptom Management in Patients Undergoing Hematopoietic Stem Cell Transplantation at the Hospital Israelita Albert Einstein.

Nelson Hamerschlak

(Participants aged 18 and older)

Introduction

You are being invited to participate voluntarily in the research entitled "Impact of Yoga and Gentle Massage Practices on Symptom Management in Patients Undergoing Hematopoietic Stem Cell Transplantation at the Albert Einstein Israelite Hospital." The main objective of this study is to assess the impact of incorporating yoga and gentle massage practices on the symptom control of patients undergoing Hematopoietic Stem Cell Transplantation (HSCT), also known as Bone Marrow Transplantation (BMT). We also aim to evaluate patient satisfaction and experience after HSCT. For these assessments, we will use questionnaires on symptoms, quality of life, religiosity, and satisfaction. The questionnaires will be available digitally through the secure REDCap Einstein platform, which is used for electronic data collection, management, and dissemination of research data. The only printed document will be the Qualitative Report, which will be provided for you to describe your experience with Integrative Medicine.

In this study, patients will be divided into 2 groups (randomized selection):

Group A (control): Will receive standard treatment for HSCT and 8 visits from integrative therapists until D+21 of hospitalization. These therapists will remain in the patient's room, able to interact, but without offering integrative practices. After D+21, these patients will receive 8 sessions of integrative practices at the bedside, or, if they are discharged after D+21, they will be treated in the Integrative Medicine room, located on the 2nd floor of Block A at the Albert Einstein Israelite Hospital - Morumbi Unit. If any patient in this group requires Integrative Medicine care during HSCT, they can request it and will be withdrawn from the research.

Group B (intervention): Will receive standard treatment for HSCT as well as yoga and gentle massage practices during the same period until D+21, with 8 visits from integrative therapists who will conduct yoga and gentle massage sessions.

Purpose of the Study

This study may provide valuable information to better structure care programs and interventions addressing the specific needs of patients undergoing Bone Marrow Transplantation.

This document (Informed Consent Form) provides important information to help you decide whether or not you want to participate in this research. After reading, if you have any questions, please feel free to ask us. This contact can be made now, before your signature, or at any time with the responsible researcher or any other study professional. The decision to participate in the research is voluntary. You can refuse to participate or withdraw your consent at any stage of the research without any penalty or harm to your care.

Procedures Performed in this Study

To achieve the objectives of this research, you will need to answer 5 different questionnaires during the HSCT period: 2 of them will be completed on the day of admission and on D+21 (or at discharge); 1 questionnaire will be answered before and after each session of yoga and gentle massage practices; the other 2 will be completed only on Day +21 (or at discharge). We will also need some personal information and information about your current and past medical history. These data will be extracted from your medical record during hospitalization.

Risks and Inconveniences

The expected risks, if any, for the procedures in this study (yoga and gentle massage) and in responding to research questions are minimal. The only likely inconvenience is the time spent filling out the questionnaires.

Benefit of Treatment

Participants will not directly benefit from the proposed research, but others may benefit from the knowledge gained.

Participant Rights

There will be no financial charge for your participation in this study, nor will there be any form of remuneration for your participation. By signing this form, you do not waive any legal rights.

Confidentiality

The study team will have access to information contained in your medical record. However, we guarantee the confidentiality of your data. If necessary, your identification will be anonymized using numbers/letters. The data obtained will be treated under strict security conditions. Your anonymized data may also be shared with groups/people associated with this research study or involved in the review of results: researchers, members of the Research Ethics Committee, representatives of federal government agencies, as required by law. If new information arises that may be important for your participation in the research, you or your legal representative will be informed immediately.

Required Approvals

This study has been approved by the Research Ethics Committee (CEP), CAAE (Certificate of Presentation for Ethical Appreciation) number 5.740.760, whose function is to ethically evaluate studies involving human subjects.

For any general questions and/or questions related to participant rights, please contact the Research Ethics Committee at telephone number 11 2151 3729 or by email at: cep@einstein.br.

For any study-related questions, please feel free to contact the researcher responsible for conducting this study: Maria Ester Azevedo Massola, telephone (11) 2151-3272 from 10:00 AM to 4:00 PM or by email at: medicinaintegrativa@einstein.br.

Consent Signatures

I have been informed of all the details related to the study to which I will be subjected.

I will receive a signed and dated copy of this Informed Consent Form.

Participant's Research Name: _____

Participant's Research Signature: _____

Date of Signature: //____

Researcher's Name: _____

Researcher's Signature: _____

Date of Signature: //____

If necessary:

Legal Representative's Name: _____

Legal Representative's Signature: _____

Date of Signature: //____