Informed Consent Form

EU5492-21: A Feasibility Study of Chaplain-Delivered Compassion Meditation for Patients Receiving Stem Cell Transplantation

NCT Number: NCT05274763

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Emory University
Consent to be a Research Subject

Title: **A feasibility study of Chaplain-delivered compassion meditation for patients receiving stem cell transplantation.**

IRB #:00003563

Principal Investigator: Jennifer S. Mascaro, Department of Family and Preventive Medicine, Emory University

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EPEX#- 62568

Introduction and Study Overview

Thank you for your interest in our medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any clinical pastoral education (CPE) benefits. If you decide not to take part in this study, your educator will continue to supervise you and you will remain in your assigned peer group.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study principal investigator or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with others. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

Study Overview:

The purpose of this study is to examine the adoption, extent of implementation, and fidelity of chaplain-delivered CCSH (Compassion-Centered Spiritual Health). CCSH is a chaplain-delivered meditation program that includes mindfulness and compassion practices and is designed to be compatible with any (or no) religious beliefs. The study is funded by the National Institute of Health and will take about 8 months to complete. You are being asked to volunteer because you are a chaplain resident with Spiritual Health at Emory Healthcare. Chaplains will deliver between four and eight 30-minute sessions (2-4/week) of CCSH to approximately 50 adult patients with multiple myeloma or lymphoma during their admission for autologous HSCT (Hematopoietic stem cell transplantation). Based on the interviews with staff, we will work within the cancer unit's workflow to minimize any interference with medical care. Chaplains will complete a fidelity checklist after each session to report which of the key intervention activities were completed. To rigorously assess fidelity, I will collect audio recordings of all CCSH sessions. All sessions will be transcribed verbatim, and two CCSH experts will independently evaluate the extent to which chaplain residents deliver CCSH with fidelity in a random subset of 50% of the sessions.

If you agree to be in this study, we may contact you about other studies related to this project. If you are contacted, you may choose to participate or decline to participate. Your participation in this study will not be affected by the decisions that you make about any other study related to this project. You can take a copy of this consent form to keep and review at any time. Feel free to take your time thinking about whether you want to participate in the study. By signing this form, you will not give up any legal rights.

What will I be asked to do?

This study will take place in the Emory Healthcare CPE sites. It will involve the following:

1. This study will be explained to you in detail, and if you are willing to participate, we will ask that you sign this consent document after discussing the study in detail and having all your questions answered.

2. Chaplains will deliver between four and eight 30-minute sessions (2-4/week) of CCSHto up to 50 adult patients with multiple myeloma or lymphoma during their admission for autologous HSCT. Chaplains will complete a fidelity checklist after each session to report which of the key intervention activities were completed

What are the possible risks and discomforts?

Hematopoietic stem cell transplant (HSCT) is among the most physically and mentally arduous cancer treatments and patients experience a multitude of acute physical symptoms that negatively impact their QOL and psychosocial well-being.[17-19] We do not have any reason to believe that CCSH will increase patients' physical, psychological, social, legal, or economic risks. Patients may become upset during the CCSH interventions due to the nature of their treatment, diagnosis, and any emotional discomfort associated with thinking about their disease. However, CCSH has been widely used in usual care in the hospital for 12 months and the chaplains are trained in delivering this type of 'talking therapy'. CCSH is widely associated with low levels of distress.

Risks to confidentiality: The questionnaires that subjects will fill out as part of this study will contain personal information, and participants will have private pieces of audio recorded. We acknowledge that it could be embarrassing if this information were to become public or fall into the hands of someone not associated with the study. We will take the following steps to prevent this from happening: All information obtained from patients will be kept strictly confidential and will be de-identified and stored by a randomly assigned study number, such that these data will be anonymous at all times during data entry and analysis. The key used to link the study number with subject identification will be stored in a password protected, secure database accessible only to study researchers. The key will only be used in the case of study personnel needing to identify a subject and not for data analysis. In addition, all data, including personal identifiers (i.e., name, address, email contact details), will be maintained in secure password-protected electronic files stored on a secure computer system that can only be accessed by study researchers. Emory Spiritual Health supervisors and others in the spiritual health department (other than members of the research team) will not have access to the key nor will they receive any study data.

New Information:

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits:

Importance of integrative treatment for depression and quality of life (QOL) in cancer. Compassion meditation can be an eminently feasible adjunctive intervention for depression and QOL.

Compensation:

Participants will not be compensated for their participation in this study.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

Medical Record

Research records are not part of your medical record, and we will take reasonable steps to keep a copy of this consent and HIPAA authorization form you sign out of Emory University Hospital and Winship Cancer Institute's medical records system. If we aren't successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them.

Costs
There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- or for any other reason.

Contact Information:
Contact Dr. Jennifer Mascaro at [redacted]

- if you have any questions about this study or your part in it;
- if you feel you have had a research-related injury;
- if you have questions, concerns or complaints about the research.

Contact the Emory Institutional Review Board at [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care at Saint Joseph's Hospital of Atlanta and have a question about your rights, please contact [redacted] at the Emory Saint Joseph's Hospital Research Committee via phone at [redacted]

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Do you agree to be a participant in this research study? **yes** ☐ **no** ☐