Reducing Persistent Fatigue Following Hematopoietic Stem Cell Transplantation

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Protocol Title: Reducing Persistent Fatigue Following Hemopoietic Stem Cell Transplantation

DF/HCC Principal Investigator(s) / Institution(s): Ashley Nelson, Ph.D. / Massachusetts General Hospital

RCT Verbal Consent

INTRODUCTION AND KEY INFORMATION

Hello—is [*name of patient*] there? Hi, my name is [*study staff name*]. **I** work at the MGH Cancer Center, and I am calling to invite you to take part in a research study that [*name of oncologist*] thought you might be eligible for. We are conducting a quality-of-life study to test an intervention for fatigue in stem cell transplant patients. I can tell you more about the study over the phone for a few minutes now, or I can call back at another time if there is a time that is more convenient. If you are interested in the study, you would enroll over the phone.

If YES: Continue to Eligibility Screening section below.
If NO: Is there a better time in the coming days that I could give you a call back?

If YES: Schedule time to call back.
If NO: Thank patient for their time and end call.

ELIGIBILITY SCREENING

Our transplant team at MGH is studying quality of life in stem cell transplant survivors. The most common side effect from transplant that patients experience is fatigue, which can impact many different aspects of a patient's life.

I have one question that we ask to get a sense of whether the study might be a good fit for you. This is optional and completely confidential. If you were to rate your fatigue severity over the past week on a 0 to 10 scale, where 0 is no fatigue and 10 is as fatigued as you could be, how would you rate your average fatigue?

If <4: Thank you for your response. At this time, you are not eligible for the study; however, fatigue is a symptom that may change over time. Would it be okay if we reach out to you at a future visit to check in with your fatigue level at that time? Thank you very much for your time today. Please feel free to reach out with any questions or concerns related to the study and have a wonderful day.

If >=4: Thank you for your response. Based on your fatigue level, it sounds like you may be a good fit for this study. Is now an OK time to further discuss the details of the study?

If YES: *Continue below*

If NO: Is there a better time in the coming days that I could give you a call back?

BRIEF STUDY DESCRIPTION

Our MGH team previously developed a program to address fatigue in transplant survivors to better support patients. The purpose of this study is to assess whether a cognitive-behavioral intervention is feasible and effective at managing fatigue and improving quality of life in participants following hematopoietic stem cell transplant. In order to determine this, participants will be randomized into two groups: one will continue usual care, one will receive the fatigue intervention. Individuals randomized to the fatigue intervention will receive up to 10 individualized counseling visits over 12 weeks covering a variety of topics which will be conducted over a secure telehealth videoconferencing system.

If you decide to participate in this research, you will be asked to complete a series of questionnaires to measure your fatigue, fatigue-related symptoms, and quality of life at three times: baseline, 3 months, and 5 months after you enrolled, regardless of which group you are assigned to. Study questionnaires will be completed in the clinic, remotely via secure email link, or over the phone with assistance provided as needed. In addition, participants of the fatigue intervention will be invited to complete a post-program exit interview which will help the study staff to better understand your experience with the intervention. This interview can be completed by phone.

Taking part in this research study will not lead to added costs to you or your insurance company. There is no added cost for this research study. Should you decide to decline participation in this study, this decision will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

Does this sound like something you might be interested in?

If patient interested: provide study details.
If patient interested but not available to talk at this time: re-schedule call.
If patient not interested in participating: thank patient, end call.

STUDY DETAILS

You are invited to take part in in this research study because you were treated with hematopoietic stem cell transplant and are currently experiencing moderate to severe fatigue. Fatigue is the most common symptom voiced by patients after a stem cell transplant. Individuals living with moderate to severe fatigue often describe feeling overwhelmed and frustrated by their symptom experience which also often interferes with everyday routines. Our research team at the Massachusetts General Hospital Cancer Center is conducting a Pilot Study to examine a cognitive-behavioral intervention designed to help address the fatigue many patients experience following a stem cell transplant.

This research study is being conducted to compare two types of care – the study intervention versus usual care. The main goal is to see if the cognitive behavioral intervention is manageable and effective at reducing fatigue and improving quality of life. It is expected that up to 63 people who are experiencing fatigue following stem cell transplant will take part in this research study.

An institution that is supporting a research study either by giving money or supplying something that is important for the research is called the "sponsor." The sponsor of this protocol is the National Heart, Lung, and Blood Institute of the NIH and is providing funding through a research grant.

Now I'd like to tell you more about the research study. If you decide to participate, the study will involve several steps.

A. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the research starts: Prior to verbally consenting, the study team reviewed your medical record to determine that you were potentially eligible to participate in this research study. We also asked your oncology team for permission to approach you to participate in the study. You do not have to participate in this study. If you do not want to participate in this study, it will not prevent you from receiving your usual care.

After verbally consenting: At a time that is convenient for you, you will be asked to complete a baseline assessment, which contains questions about yourself such as your race, ethnicity, religion, relationship status, education, income, and living situation either written or on the computer. The questionnaire also contains questions about your fatigue, fatigue-related symptoms, and quality of life. If you are not able to use the computer, you may complete the baseline assessment over the phone with the study staff recording the answers or by mail. Your responses will remain confidential. Our study staff members are trained in confidentiality and research ethics to ensure protection of your confidentiality. You will not be able to participate in this study without completing this questionnaire. We expect this

questionnaire will take you approximately 20 minutes to complete.

Assignment to study group: After you complete the baseline assessment, you will be informed about the study group to which you have been assigned. Because no one knows whether this intervention is manageable and effective, this assignment is random:

- Usual Care
- Fatigue Intervention

Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor your doctor will choose which group you are assigned to. You will have an equal chance of being placed in either group.

If you are randomized to usual care:

- You will receive usual care, which means you will continue to have your standard medical visits, but you will also receive material from the MGH Bone Marrow Transplant Survivorship Program describing common medical causes of fatigue after transplant and recommendations for management.
- You will be asked to complete assessments at 3 months and 5 months after you enrolled in the study. These questionnaires are expected to take up to 20 minutes to complete. You will have the option of completing these questionnaires during a routine clinic visit, or remotely over the phone or through a secure web link.

If you are randomized to the Fatigue Intervention:

- You will be asked to complete a brief test call with the videoconferencing system to make sure that you are able to use the software. If you are unwilling or unable to use the videoconferencing software, you will not be able to participate in this study.
- You will meet with a behavioral health counselor for up to 10 sessions over 12 weeks for approximately 20 to 45 minutes per session. The first visit may take up to 90 minutes in order for the behavioral health counselor to assess and better understand your fatigue and to introduce the intervention to you. The sessions will take place over zoom. The study team will work with you to coordinate and schedule these visits to accommodate you.
- The study sessions will cover a variety of topics tailored to you, and may include setting goals, managing sleep, increasing physical activity, dealing with difficult thoughts, navigating social relationships, and coping with transplant and fear. During sessions, your counselor will talk to you about these topics, review home practice of skills, and help to problem solve barriers to skill use. You will also receive a study workbook to further assist the intervention.

- These study visits will be audio-recorded so we can ensure that the intervention is being delivered appropriately for all study participants. The audio-recording will remain confidential and will only be accessible by study staff. The audio recordings will not be shared with your medical team or others.
- You will be asked to complete assessments at 3 months and 5 months after you enrolled in the study. These questionnaires are expected to take up to 20 minutes to complete. You will have the option of completing these questionnaires during a routine clinic visit, remotely over the phone, or through a secure web link.
- Those randomized to the fatigue intervention will be asked to complete a brief interview with a trained member of the study staff about your experience with the intervention, materials, questionnaire, and study logistics.
- The interview will take place over zoom or on the phone. The study team will work with you to coordinate and schedule this one-time interview to accommodate you. The interview will be audio recorded to analyze and look back on the data. They will also be de-identified to protect participant confidentiality.

After the final questionnaire: Your oncologist, as well as the study team, will be available to discuss any questions or concerns that you may have. Once you finish the last questionnaire, you will not be contacted by us again. We would like to keep track of your medical status by reviewing your electronic medical record up to 180 days after enrolling in the study.

What are my options?
Instead of being in this research study, you have other options which may include the following:

- Decide not to participate in this research study
- Participate in another research study

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions at any time.

B. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

There are risks to taking part in any research study, including the possibility of a breach of confidentiality. However, we will take steps to minimize the risk.

This particular study does not have any physical risks. There is some risk that you may experience anxiety or distress when discussing certain topics during the study sessions, such as your illness, when talking about your symptoms, or while filling out the study questionnaires. If this occurs, please discuss your feelings with your doctor or a member of the research team and they will try to help you with any

issues you may be having. You may skip any questions on the questionnaires that cause you distress or discomfort. If you feel upset by any aspect of the study, the counselors and licensed providers, along with your oncologist, will be available to talk with you. We can arrange for you to meet with our social worker for additional counseling if needed.

During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to verbally consent with a new form that shows that you have been informed of new information relating to this research study.

Research studies also have a risk of some loss of privacy. To help prevent loss of privacy, your name will not be recorded on any study documents. We will assign a research identification number to all participants that will be used in all study documentation. All files, including this consent form and study questionnaires will be stored in secure electronic files. Only the study team will have access to the file password linking research identification numbers to your name.

C. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?

You may be taken off the research study for any reason including:

- It is in your best interest
- The study intervention or procedures are found to be unsafe or ineffective
- There is any problem with following study intervention and procedures
- Your condition worsens
- A decision is made to end the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

You have the right to choose not to sign this form. If you decide not to sign this

form, you cannot participate in this research study.

If you choose to not participate, or if you are not eligible to participate, or if you withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise

entitled. You will still be able to receive routine supportive care, including access to social work services, if you do not participate.

D. WHAT ARE THE BENEFITS OF THIS RESEARCH STUDY?

Taking part in this research study may or may not benefit you. The intervention is designed to help participants manage and potentially reduce persistent fatigue following hematopoietic stem cell transplant. We hope the information learned from this research study will provide information about how to address the fatigue patients experience after HCT. This study may help researchers learn information that could help people in the future.

E. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will not be paid for participating in this study.

F. WHAT ARE YOUR COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company.

You will not be charged for the following that are part of this research study:

- Seeing the counselor for fatigue after stem cell transplant

You or your insurance company will be charged for other portions of your care during this research study that are considered standard care.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services:

- Massachusetts General Hospital: (617) 726-2191

G. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

There are no physical risks to taking part in this study. If you think you have been injured because of taking part in this research study, tell the person in charge of

this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments may be billed to you or your insurance company. You will be responsible for deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by verbally consenting.

H. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research doctor or study staff as listed below:

Massachusetts General Hospital
Ashley Nelson, PhD: (617) 643-8574

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

I. RETURN OF RESEARCH RESULTS

If you are interested, you may request to see the results of the research study, and the study team will provide you with a results summary upon completion of the research study.

J. CLINICALTRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

K. FUTURE USE OF DATA AND SPECIMENS

Your personal information collected during this study may be stored and used for future research. Any personal identifiers will be removed, before they are shared, so that the information cannot be linked back to you.

Investigators, including investigators from collaborating institutions, can request this data for new research.

You will not be asked to provide additional informed consent for the use of your de-identified information or samples in future research.

L. CONFIDENTIALITY

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file. It may also become part of a research database.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers. We will not include information that identifies you in any publications or to any researchers who request the data to do additional research.

Your de-identified data may also be placed into one or more publicly accessible scientific databases. Through such databases, researchers from around the world will have access to de-identified samples or data for future research.

There is a risk that deidentified research data that is shared with outside collaborators may be reidentified. When deidentified data and specimens are shared with outside collaborators agreements limit what the outside collaborators can do with the information to help prevent reidentification.

M. FINANCIAL DISCLOSURES

There are no financial disclosures or conflicts of interests to report.

N. CERTIFICATE OF CONFIDENTIALITY (CoC)

To help protect your privacy, we have been issued a Confidentiality Certificate from the National Institutes of Health (NIH). With this Certificate, the researchers on this study cannot be forced (for example, by court subpoena) to disclose information that may identify you in federal, state, or local civil, criminal, administrative, legislative or other proceedings.

Disclosure will be necessary upon request of a United States federal or state

government agency sponsoring the project that will be used for audit or program evaluation purposes or to meet the requirements of the federal Food and Drug Administration (FDA)

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family or even the research doctor from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or employer learns about your participation, and obtains your consent to receive research information, then we cannot use the Certificate of Confidentiality to withhold this information. This means that you and your family must actively protect your own privacy.

The Certificate of Confidentiality cannot be used to prevent disclosure to state or local authorities when there is a duty to report concerns of abuse, neglect, self-harm or a danger to others.

O. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAAAUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records
- New health information created from study-related visits and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm);
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the

study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s): National Heart, Lung, and Blood Institute of the NIH
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to

satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. **For how long will protected health information about me be used or shared with others?**

   - There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. **Statement of privacy rights:**

   - You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: “Whom do I contact if I have questions about the research study?”

P. You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: “Whom do I contact if I have questions about the research study.

Q. DOCUMENTATION OF CONSENT

Do you have any other questions about the study?

Would you like to agree to do the research study?

Accepts participation in the study
Declines participation in the study
Is ineligible for the study
Is unsure about participation in the study (arrange for additional contact with patient)

Do you have any other questions or concerns?

_____ _____

Date of Verbal Consent Name of Consenting Investigator

_____

Signature of Consenting Investigator