PROTOCOL TITLE: MULTIMODAL MOBILE INTERVENTION APPLICATION (APP) TO ADDRESS SEXUAL DYSFUNCTION IN HEMATOPOIETIC STEM CELL TRANSPLANT SURVIVORS

PRINCIPAL INVESTIGATOR: AREEJ EL-JAWAHRI

DATE OF CONSENT DOCUMENT: 2/3/2022

CLINICAL TRIALS.GOV: NCT03967379

Protocol Title: Multimodal Mobile Intervention Application (App) To Address Sexual Dysfunction in Hematopoietic Stem Cell Transplant Survivors

DF/HCC Principal Research Doctor / Institution:

Areej El-Jawahri MD/MGH

Corey Cutler MD, MPH/DFCI

Ajoy Dias MD/BIDMC

Main Consent

INTRODUCTION AND KEY INFORMATION

All research is voluntary. It is your choice whether you take part in this research or not.

The following is a short summary of this research study to help you decide whether you would like to be a part of this study. More detailed information is provided later in this form.

For purposes of this research, you will be referred to as a "participant."

1. Why am I being invited to take part in a research study?

You are invited to take part in in this research study, because you have undergone stem cell transplantation.

2. Why is this research being done?

Frequently survivors of stem cell transplantation report significant problems with their sexual function that impacts their quality of life, mood, and their intimacy and relationship with their partners. These issues can be very distressing to patients and their loved ones. The study doctors want to know if the use of a mobile app intervention focused on improving sexual function may improve your overall care.

3. What does this research study involve and how long will it last?

This research study involves screening for eligibility and a series of questionnaires to measure your quality of life and sexual function. Study questionnaires can be completed in the hospital, clinic, over email, or telephone with assistance as provided.

You will be in this research study for up to one year after you consent. Each questionnaire should take you about 20 minutes to complete. We will keep track of your medical information only by reviewing your medical record for the next 2 years.

It is expected that about 60 people will take part in this research study.

Information about you and your health is personal and private. Generally, it cannot be obtained without your written permission. By signing this form, you are providing that permission and your information may be obtained and used in accordance with this informed consent and as required or allowed by law. This means that researchers may obtain information regarding your past medical history, as well as specimens and samples from previous health care providers such as hospitals and labs.

4. What are the risks to participating in this study?

There are risks to taking part in any research study. However, this particular study does not have any physical risks. You may find it upsetting to answer some of the items on the questionnaire. The research assistant will be available to you during your participation in the study. If you feel upset by any aspect of the study, the research assistant, along with your oncologist, will be available to talk with you. We can arrange for you to meet with our psychologist 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 sign a new consent form that shows that you have been informed of new information relating to this research study.

Major known risks to participating in this research study include:

- Disclosure of sensitive personal information may result is a loss of privacy
- Possible emotional distress due to personal questions
- Significant amount of time required to complete questionnaires (online and/or in person)

5. Will being in this study benefit me in any way?

Taking part in this research study may or may not benefit you. We hope the information learned from this research study will provide more information about how a mobile app intervention can improve our management of sexual health symptoms for stem cell transplant survivors.

We do not know if taking part in this study will benefit you. This study may help researchers learn information that could help people in the future.

6. What are my options?

If you decide to participate, please sign and date at the end of this form.

We will give you a copy and you can refer to this consent form at any time during the research study.

If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you back to your primary doctor.

A. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is being done to evaluate whether the use of a mobile app can help transplant survivors experiencing sexual health problems.

In this research study, we are:

- Testing whether using the mobile app is feasible in addressing sexual health problems in transplant survivors.
- The app is called "SHIFT: Sexual Health and Intimacy Following Transplant." It was developed by clinicians at MGH.
- Previous research shows that mobile apps can be effective in helping people with issues like anxiety and we want to see if we can similarly address sexual health problems.
- We are hoping to learn if using the app to address sexual health problems is acceptable and useful to transplant survivors.

The main purpose of this study is to compare two types of care – the mobile app intervention versus enhanced standard care which includes having one time visit with a transplant clinician to conduct a brief medical examination and asses the needs for medications or treatments to address sexual health problems.

B. WHAT OTHER OPTIONS ARE THERE?

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 now and at any time in the future.

C. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Research Study Plan:

Before the research starts: Prior to signing this consent form, our research team reviewed your medical record to determine that you were eligible to participate in this research study. We also asked your oncology team for permission to approach you to participate in the study.

After you sign this consent form: You will first be asked to answer a few questions about yourself on a laptop tablet computer, such as your race, ethnicity, religion, relationship status, education, income, and living situation.

You will then be asked to complete a questionnaire which contains questions about your mood, quality of life (including your general, physical, social, and emotional well-being), and sexual function. If you are not able to use the laptop, you may fill out the baseline questions on paper.

Assignment to study group:
Because no one knows which of the study option is best, you will be randomized into one of the study groups:

- Enhanced Standard Care
- Multimodal Intervention mobile app to address sexual health problems

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 arm you are assigned to. You will have an equal chance of being placed in either group.

Study procedures:
If you are randomized to enhanced standard care:

- You will receive standard oncology care by your oncology team
- You will attend a clinic visit with a transplant clinician specializing in sexual health who will conduct a brief examination and assess the need for any treatments or medications to address your sexual health problems.
- You will be asked to complete study questionnaires on the laptop computer at 8 and 12 weeks after noted clinician consult. These questionnaires are expected to take up to 20 minutes. You will have the option of completing these questionnaires during one of your routine clinic visits, or remotely through a secure web link.

If you are randomized to the Multimodal Intervention app:

- You will receive standard oncology care by your oncology team.
- You will attend a clinic visit with a transplant clinician specializing in sexual health who will conduct a brief examination and assess the

need for any treatments or medications to address your sexual health problems.

- You will be provided with instructions on how to use the mobile app. If you don't have an i-pad, you will be provided with an i-pad that allows you to engage with the mobile app at your convenience at home over an eight week period.
- You will be asked to complete study questionnaires on the laptop computer at 8 and 12 weeks after clinician consult. These questionnaires are expected to take up to 20 minutes. You will have the option of completing these questionnaires during one of your routine clinic visits, or remotely through a secure web link.

After the last assessment:
Your oncologist, as well as the research team, will be available to discuss any questions or concerns that you may have. Once you finish your last questionnaire at 12 weeks, we will only contact you if you were assigned to the intervention and we would like you to participate in a 20–30-minute interview about your experience using the mobile app (See Section P: Consent to optional studies). Once you complete the last questionnaire or interview you will not be contacted by us again. We would like to keep track of your medical condition by reviewing your electronic medical record for the next 2 years.

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

There are risks to taking part in any research study. However, this particular study does not have any physical risks. You may find it upsetting to answer some of the items on the questionnaire. The research assistant will be available to you during your participation in the study. If you feel upset by any aspect of the study, the research assistant, along with your oncologist, will be available to talk with you. We can arrange for you to meet with our psychologist 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 sign a new consent form that shows that you have been informed of new information relating to this research study.

E. 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 considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments 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.

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

You will not be paid for participating in this study.

G. WHO IS SUPPORTING THIS RESEARCH?

Massachusetts General Hospital is supporting this research study by providing funding.

H. 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 billed or incur any co-pays for your visit with the transplant clinician to address sexual health problems as part of this study.

I. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result 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 signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

J. 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:
- Areej El-Jawahri, MD: (617) 726-2000, beeper #18734

Dana Farber Cancer Institute
- Corey Cutler, MD, MPH: (617) 632-3470 beeper #41115

Beth Israel Deaconess Medical Center
- Ajoy Dias, MD: (617) 667-9920, beeper #35984
-

24-hour contact information:

Massachusetts General Hospital:
- Areej El-Jawahri, MD: (617) 726-2000, beeper #18734

Dana Farber Cancer Institute
- Corey Cutler, MD, MPH: (617) 632-3470 beeper #41115

Beth Israel Deaconess Medical Center
- Ajoy Dias, MD: (617) 667-9920, beeper #35984

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.

K. RETURN OF RESEARCH RESULTS

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found.

L. CLINICALTRIALS.GOV (CT.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.

M. 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 DF/HCC research database called CORIS.

The questionnaires will not become part of your medical record but will be stored in a research file with a specific study code identifier without your name.

Your answers to all the survey questionnaires will remain confidential.

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 the researchers who request the data to do additional 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.

N. GENETIC RESEARCH

This research will not involve genomic or germline testing.

O. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

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 tests, procedures, 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); and
- 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).
- 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?"
- 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?"

P. CONSENT TO OPTIONAL RESEARCH STUDIES:

You are being asked to participate in an optional study. If you decide not to participate in the optional study, you can still participate in the main research study. Please take your time to make your decision and discuss it with others and your oncology team.

Your participation in this optional research study is voluntary, and you will not be penalized or lose any benefits if you refuse to participate or decide to stop.

Optional Study:
We may ask you to participate in a brief interview with the research staff that will last about 20 to 30 minutes. This interview will only be conducted with 10 patients who are assigned to use the SHIFT mobile app intervention, and thus you can choose not to participate. The interview will be audio-recorded and transcribed. We will ask you about your perceptions and experience using the sexual health mobile app to get a sense of your overall satisfaction with the application.

Please indicate whether you want to take part in this optional research study.

☐ Yes _____Initials _____Date

☐ No _____ Initials _____Date

Q. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

_____ _____

Signature of Participant Date
or Legally Authorized Representative

_____

Relationship of Legally Authorized Representative to Participant

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

_____ _____

Second Signature of Legally Authorized Representative Date

_____

Relationship of Legally Authorized Representative to Participant

To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ 1b) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate