Official Title	Seamless Phase II-Phase III Randomized Clinical Trial to Identify and Confirm the Most Promising Novel Intervention to Alleviate Morbidity and Mortality after Allogeneic Hematopoietic Cell Transplantation Among Older, Medically Infirm, or Frail Patients with Hematological Diseases
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Fred Hutchinson Cancer Center

Consent to take part in a research study:

Seamless Phase II-Phase III Randomized Clinical Trial to Identify and Confirm the Most Promising Novel Intervention to Alleviate Morbidity and Mortality after Allogeneic Hematopoietic Cell Transplantation Among Older, Medically Infirm, or Frail Patients with Hematological Diseases

"ACE BMT" Study

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Emergency Number (24 hours): (206) 598-8902

Important things to know about this study

You are invited to participate in a research study because you have a blood disease that can be treated with transplantation of blood stem cells from a donor (allogeneic stem cell transplantation [SCT]) and because you have at least one of the following:

- 65 years of age or older.
- Health problems other than cancer, such as heart or lung disease.
- A degree of weakness as detected by a slow walk speed test.

In this research study, we are examining if an additional level of supportive care added to usual care during the time of transplant can help make you feel better after allogeneic SCT.

People who agree to join this study will be randomly assigned to an intervention arm or usual care only arm. Randomization means we will use a computer system to assign you to one of the two study arms. It is just like flipping a coin.

If you are assigned to the intervention arm, then this intervention will last for 10 weeks, roughly 2 weeks before and 8 weeks after your transplantation. The intervention will involve attending one weekly visit by a palliative and supportive care specialist to improve your health.

Once you join the study, you'll be asked to complete questionnaires and tests at five different timepoints from between the time you enroll on the study up to 1 year.

You do not have to join this study. We will give you details about the purposes, procedures, risks and possible benefits related to this study. We will explain other choices that you have. Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We invite you to join this research study

We invite you to join this research study because you have been diagnosed with a blood disease and have been referred to receive allogeneic SCT. Up to 617 people will join this study.

Research is not the same as treatment or medical care. The purpose of a research study is to answer scientific questions.

You do not have to be in the study. You are free to say "yes" or "no", or to drop out after joining. If you say "no," you would have no penalty or loss of benefits. Whatever you decide, your regular medical care would not change.

Why are we doing this study?

We are doing this study to examine if a supportive care intervention improves your quality of life after allogeneic SCT. Allogeneic SCT can provide cure to many patients with blood diseases but it can also worsen quality of life or cause life-threatening complications. These undesirable outcomes are more likely to happen in patients of 65 years of age or older, those with multiple other medical problems, or those who are feeling weak and frail.

In this study, we are testing a novel intervention of supportive care that ideally starts before and continues after the SCT with the aim to prove our hypothesis that such intervention could help patients feel better after their SCT.

Our prior research suggests that this additional supportive care may help you and other patients tolerate SCT better. However, since we do not know for sure whether this intervention will benefit patients or not, we have to test it in a randomized fashion comparing the intervention to the usual care that patients currently receive.

After joining the study, you will be assigned by computer system to either the intervention arm or Usual Care Only (UCO) arm. The intervention arm includes Supportive and Palliative Care (SPC).

Participants assigned to the intervention arm: You will receive Supportive and Palliative Care (SPC), which is a specialized medical care. This type of care is focused on providing relief from the symptoms and stress of a serious illness or procedure. The goal is to improve quality of life for the patient and might also improve quality of life of their family.

SPC is provided by a provider, a doctor or a physician assistant, who have a special training to work together with a patient's cancer doctors to provide an extra layer of support. It is appropriate at any age and at any stage in a serious illness, and it can be provided along with curative treatment.

SPC has been studied and proven successful in improving quality of life and prolonging life of patients with other types of cancer, such as lung cancer. But SPC care has not been tested with allogeneic SCT for older patients or those patients with medical comorbidities. Therefore, we are proposing in this trial to study SPC while patients are receiving allogeneic SCT.

Participants assigned to UCO arm: You will not receive any study related interventions. You will receive the standard care we provide to all of our transplant patients.

This is a randomized study. This means you would have a 50% chance of receiving UCO. If you join this study, you will not be allowed to choose the group to which you are randomized.

What research tests, procedures, and treatments are done in this study?

If you agree to be in this study, we will collect the following information about you:

- Questionnaire. We would ask you to fill out five questionnaires. One when you join the study and again at one month, three months, six months and twelve months after your allogeneic SCT. Some of the questions may be sensitive. Questions that make you feel uncomfortable would not have to be answered. The questionnaire can be sent to you in paper version, electronically or read to you. It will take approximately fifteen minutes to complete.

- 6-Minute Walk Test. We would ask you to complete this walk test three times. Once when you join the study and again at three months and twelve months after your allogeneic SCT. You will meet face-to-face with study staff and be asked to walk along a corridor as far you can for six minutes.

- 4-Meter Walk Test. We would ask you to complete this walk test four times. Once when you join the study and again at three months, six months and twelve months after your allogeneic SCT. You will walk the distance of four meters (approximately 13 feet) three different times at each assessment time-point. If you are not able to meet face-to-face with study staff, an at home walk test will be mailed to you. This is the same test as the one with study staff. This will take five minutes to complete.

- Up and Go Test. We will ask you to complete this test a total of four different times. Once when you join the study and again at three months, six months and twelve months after your allogeneic SCT. This measures how long it takes you to stand up from an armchair, walk a distance of approximately 10 feet, turn, walk back to the chair and sit down again. This test takes about two minutes to complete.

- Measured Grip Strength Test. We will ask you to complete this test a total of four different times. Once when you join the study and again at three months, six months and twelve months after your allogeneic SCT. You will squeeze a dynamometer a maximum of 3 times with your dominant hand. This test will take about five minutes to complete.

- Cognition Assessment. We will ask you to complete this test a total of four times. Once when you join the study and again at three months, six months and twelve months after your

allogeneic SCT. This test is a total of 6 questions and will take less than 5 minutes to complete.

- MD Survey. Once at enrollment, we will contact your physician asking him/her to complete a survey about your style of making treatment decisions and your chance of cure.
- If your transplant is delayed, we will ask your physician to complete a survey explaining why.
- We will review your medical records to collect information about your past medical history, past treatments, and details related to your SCT.
- We may 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.
- For participants in the intervention arm, we may record intervention meetings with you for the purpose of training and to ensure that the interventions are being provided correctly to you. Only trained study staff will have access to intervention meeting recordings.
- <u>All these tests and questionnaires will be done during your regular visits to the clinic. You will not be asked to make any special visits for the purpose of the study. Some of our evaluations can be done using telehealth while you are at your residence.</u>
- **Important Note:** If your transplant is delayed, some assessments done when you joined the study will be repeated so that they accurately reflect your status close before your time of receiving a transplant. Assessments to be repeated could include the questionnaire; walk, up and go, and grip strength tests; and the cognition assessment. There will be no charges associated with repeat assessments.

If you are in the intervention arm, we would do these additional procedures:

Supportive and Palliative Care (SPC):

- We will ask you to meet with a Supportive and Palliative Care provider at least once weekly for ten weeks, starting roughly about two weeks before the transplant procedure and continuing following the procedure. This is our recommended frequency of visits to achieve the highest benefit from Supportive and Palliative Care. If you feel you want to see the Supportive and Palliative Care provider more frequently, you can ask your Supportive and Palliative Care provider or primary team to do so. If you feel you want to see the Supportive and Palliative Care provider less frequently, you can convey these wishes either directly to the Supportive and Palliative Care provider, to a study team member, or to your primary team.
- These visits will happen whether you are receiving treatment in the outpatient department or you are admitted to the hospital. The only difference will be meeting a different palliative care provider while in the hospital compared to the one you meet when you are outside the hospital. This system is done to match the need for an available provider 24 hours/day; any day of the week

while a patient is inside the hospital. This is because we assume there may be urgent needs for patients who are hospitalized.

- Prior to or during these visits, a study team member or the Supportive and Palliative Care Provider will give you a one-page survey asking you about the most pressing problem that you face or have faced in the week prior. Then, the Supportive and Palliative care provider will start the discussion focusing on your most pressing issues. These discussions could cover topics such as:
    - Your symptoms during that time. For example, pain, insomnia, nausea and how best to manage them so you can feel better.
    - If you are feeling distressed because of the transplant or anything else, and how you are coping.
    - Your preferred approach to making treatment decisions, your preferences regarding communications and coordinating care among your various medical teams.
    - Your satisfaction with the level of support you and your caregiver are receiving and how to improve this.
    - Any religious, spiritual or cultural beliefs you hold and want to follow during transplant.
    - Any other concerns you might have before or after SCT.

How long would you stay in this study?

If you join this study, you may actively participate in the study up until approximately 8 weeks after SCT. In addition, we will ask you to complete the tests and surveys mentioned above at approximately 1, 3, 6, and 12 months after SCT. There will be no other study involvement after the first year after SCT.

We would like to keep track of your medical condition for the rest of your life to fully understand the long-term effects of this study. However, you may be taken off the study and followed less frequently if one of the following happens:

- If, after you have been randomized, the date of your SCT is delayed more than 28 days from its original date.
- It is in your best interest not to continue in the study.
- You are not able to follow study procedures.
- Per your request.

If you withdraw from the study for any reason, previously collected information would remain in the study records and would be included in the analysis of results.

What are the risks?

Risks related to the study in general whether you are in the intervention or UCO arm:

- It is possible that you may find some topics upsetting while completing the questionnaires. If we learn that you are stressed or depressed based on study assessments, we will notify the study PI and your treating physician, conduct an assessment of safety and refer you to psychiatric services. You also can contact your primary doctor directly for necessary medical attention or let a member of the study team know and we will assist you in obtaining medical care.
- By downloading mobile apps, you will agree to the app developer's license terms. These applications are commercially available, and the terms would be the same as if you had downloaded them for personal use.

If you are randomized to in the intervention arm:

Non-physical risk

- It is possible that you may find some topics upsetting during the Supportive and Palliative Care meetings. If we learn that you are stressed or depressed based on study assessments, we will notify the study PI and your treating physician, conduct an assessment of safety, and refer you to psychiatric services. You also can contact your primary doctor directly for necessary medical attention or let a member of the study team know and we will assist you in obtaining medical care.
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What are the benefits?

Taking part in this study may or may not improve your health. The intervention involved in this study are known to improve mood, well-being, and/or general health. You might get direct benefit from the intervention during your SCT if you are assigned to the intervention arm.

Information from this study will help doctors learn more about what methods may improve quality of life, prolong life, or both after allogeneic SCT. Results from this study could improve results of SCT for future patients with blood diseases.

You have other choices besides this study

You can participate in other research studies (if available and you are eligible), or you can choose not to participate in any research studies.

Each of these choices has risks and benefits. You should talk to your doctor or healthcare provider about these choices.

Protecting Privacy as an Individual and the Confidentiality of Personal Information

If you join this study, some people or organizations might need to look at your medical records and research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Fred Hutchinson Cancer Center and the University of Washington.
- US National Institutes of Health, National Cancer Institute, Office for Human Research Protections, and other regulatory agencies as required.

We will do our best to keep personal information confidential. But we cannot guarantee total confidentiality.

We will not use personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

As part of this study we will collect identifiable information about you that might be used, stored or shared for the purpose of another research project. Your information will be stored and protected and only be released if the Fred Hutch IRB approves.

This research is covered by a Certificate of Confidentiality from the U.S. government. This Certificate helps protect the confidentiality of information about people who join this study. If you join the study, the Certificate means that generally we would not have to give out identifying information about you even if we were asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We could not use the Certificate to withhold research information if you give written consent to give it to an insurer, employer, or other person.

This protection has some limits. We would voluntarily provide the information:

- To a member of the federal government who needs it in order to audit or evaluate the research.
- To the funding agency and groups involved in the research, if they need the information to make sure the research is being done correctly.
- To someone who is accused of a crime, if he or she believes that our research records could be used for defense.
- To authorities, if we learn of child abuse, elder abuse, or if participants might harm themselves or others.

Would we pay you if you join this study?

We will ask you to complete 5 survey packets during the study duration of 2 years.
You will receive a payment of $20.00 for each completed and returned survey packet.
The most you would receive is a total of $100.00 if you complete and return all 5 survey packets.

Would you have extra costs if you join this study?

Palliative care visits are considered standard care for patients with cancer; hence they are payable by insurance.

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website or phone number below:

- http://www.cancer.gov or 1-800-4-CANCER (1-800-422-6237)

If you are randomly assigned to the intervention arm which includes the Supportive and Palliative Care (SPC) intervention, your visits with the Supportive and Palliative Care provider will be billed to your insurance company.

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

If you have questions about your insurance coverage, or any items you might be required to pay for, please call financial services for information. The contact information for financial services is listed at the end of this consent form.

There are no further costs for being in this study.

What if you get sick or hurt after you join this study?

For a life-threatening problem, call 911 right away or seek help immediately. Contact your study doctor when the medical emergency is over or as soon as you can.

For all other medical problems or illness related to this research, immediately contact your physician. They will treat you or refer you for treatment. You or your health insurance will have to pay for the treatment. There are no funds to pay you for a research-related injury, added medical costs, loss of a job, or other costs to you or your family. State or national law may give you rights to seek payment for some of these expenses. You do not waive any right to seek payment by signing this consent form.

You or your insurer will be billed for treatment of problems or complications that result from your condition or from standard clinical care.

You would not lose any legal right to seek payment for treatment if you sign this form.

What will my information be used for?

Your information will be used for the purpose of this study.

During this study, we do not expect any test results would affect your care, so we do not plan to return results to you.

In addition, be aware that by agreeing to participate in this study, your information could be used for future research studies or sent to other investigators for future research studies without additional consent from you. These future research studies will be reviewed by an oversight group known as an institutional review board if required by law. The information that identifies you will first be removed from your information. If you do not want your information to be used for future research studies without your consent, you should not participate in this study.

If you join this study, information about your participation would be made part of your permanent medical record. This information would include a copy of this consent form. If an insurance company or employer or anyone else were authorized to see your medical record, they would see a copy of this consent form.

Some information about you will be collected by the apps that you download and used in accordance with their privacy policies.

Your rights

- You do not have to join this study. You are free to say “yes” or “no”.
- If you get sick or hurt in this study, you do not lose any of your legal rights to seek payment by signing this form.
- During the study, we might learn new information that you need to know. For example, some information may affect your health or well-being. Other information might make you change your mind about being in this study. If we learn these kinds of information, we would tell you.
- If you join this study, you would not have to stay in it. You could stop at any time (even before you start). Your regular medical care would not change. You would have no penalty for stopping, but it would be better not to join the study if you think that you would change your mind later.

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

Your responsibilities

If you join this study, you would have some responsibilities.

- Follow the schedule of study visits and procedures.
- Tell us about side effects.

For more information

If you have questions or concerns about this study, you could talk to your doctor anytime. Other people you could talk to are listed below.

If you have questions about:	**Call:**
This study (including complaints and requests for information)	(206) 667-6298 (Dr. Mohamed L. Sorror, MD) (206) 667-7263 (ACE BMT Study Team)
Your rights as a research participant	206-667-5900 or email irodirector@fredhutch.org (Director of Institutional Review Office, Fred Hutchinson Cancer Center)
Your bills and health insurance coverage	(206) 606-6226 (Patient Financial Services)

Participant's Signature

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant:

Printed Name	Signature	Date

Researcher's Statement

I have discussed the research study, including procedures and risks, with the person signing above. A copy of the signed consent form will be given to the participant.

Person obtaining consent signature:

Printed Name	Signature	Date

Protocol: 9885
Current consent version date: 08/15/2023
Previous consent version date: 10/13/2022
Copies to: Medical Record
Participant