Informed Consent to Participate in Research

Your Name: _____

Study Title: A Phase III Randomized, Multi-center Trial Testing Whether Exercise or Stress Management Improves Functional Status and Symptoms of Autologous and Allogeneic Recipients.

Protocol: 0902

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Transplant Center

Investigator: _____

Sponsor: The National Institutes of Health (NIH), the National Heart, Lung, and Blood Institute, and the National Cancer Institute gave financial support for this research study through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN).

Introduction

You are invited to join a research study. The main goal of this study is to learn whether patients who participate in an exercise program, a stress management program, or both programs will feel better after transplant compared to patients who do not participate in either program. We also want to know what areas of your physical and emotional health might improve after transplant and how long any improvement may last.

Your participation in the study will last 6 months. Seven hundred people will participate. You will have an equal chance of being placed in one 1 of 4 different groups. Each group will receive a different program. We will explain the 4 groups in this Consent Form. All of the clinics in this study will report their results, so we can compare all of the groups at the end of the study.

Group 1	Group 2	Group 3	Group 4
General Information	Exercise	Stress Management	Exercise and Stress Management

This Consent Form will tell you about the purpose of the research, its possible risks and benefits, other options available to you, and your rights as a participant in the study. Please take your time to read and understand the information in this form before you make your decision.

Everyone who takes part in research at [insert facility name] should know that:

- Being in any research study is voluntary.
- You may or may not benefit from being in the study. Knowledge we gain from this study may benefit others.
- If you join the study, you can leave the study at any time.
- If you decide to leave the study, it will not affect your care at [insert name of facility or institution].
- Please ask the study staff questions about anything that you do not understand or if you would like to have more information.
- You can ask questions now or any time during the study.
- Please take the time you need to talk about the study with your doctor, study staff, and your family and friends. It is your decision to be in the study. If you decide to join, please sign and date the end of the Consent Form.

You may wish to discuss other alternatives with your doctor.

1. Background

This research study is sponsored by The National Institutes of Health (NIH), the National Heart, Lung, and Blood Institute (NHLBI), and the National Cancer Institute (NCI) through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN).

Previous studies suggest that patients who exercise or use stress management methods after transplant may experience better physical and emotional health than patients who do not exercise or use stress management techniques after transplant. Although previous studies suggest benefits, we don't know if you will get any benefits by taking part in this study. That is why we are doing this research study. What we learn may help to improve the quality of life of other patients after transplant.

2. Purpose

The main goal of this study is to learn whether patients who participate in an exercise program, stress management program, or a combination of an exercise and stress management program will feel better after transplant compared to patients who do not participate in either program. We also want to know what parts of your physical and emotional health improve after transplant and how long any improvement lasts.

3. The Right to Ask Questions and/or Leave the Study

You have the right to ask questions about the study at any time. If you have questions about your rights as a participant or you want to leave the study, please contact:

[Insert contact info]

Being in this study is voluntary. You can choose not to be in this study, or leave this study at any time.

If you choose to not join or you decide to leave this study, your regular medical care will not be affected in any way. If you decide to not join this study, you will still receive the usual physical and emotional care given to transplant patients.

Even if you leave the study, the information collected from your participation will be included in the study evaluation, unless you specifically ask that it not be included.

Your study doctor and study staff will be available to answer any questions that you may have about joining or leaving this study.

4. Procedures

If you decide to join this study, you will need to sign this Consent Form. We will give you a copy of the signed form to keep.

You will continue to have regular physical exams, laboratory tests, and other evaluations that are standard care by your doctor and transplant center.

Once you agree to join, we will randomly assign you to 1 of 4 groups before you have your transplant.

Group 1 will get general information about transplantation and how to take care of themselves after their transplant.

Group 2 will get information about exercise and be asked to exercise regularly after their transplant.

Group 3 will get information about stress management and be asked to use stress management methods after their transplant.

Group 4 will get information about exercise and stress management and be asked to exercise regularly and use stress management methods after their transplant.

A member of the research team will meet with you to explain details about your group and the materials you will use for the study. You will need to review some of the materials at home. We think it will take you about one hour to go through the packet of materials. If you do not have a DVD or CD player, equipment will be available in the clinic or hospital that you can use to review the materials.

Details About the Study Groups

- **Group 1 - General Information**
  If you are assigned to this group, you will get a DVD about transplantation and how you can take care of yourself after transplant. The DVD is about 45 minutes in length and covers topics such as preparing for transplant, engraftment, early recovery and long-term recovery.
- **Group 2 - Exercise**
  If you are assigned to this group, in addition to the general information DVD you will get a packet of materials along with a short (10 minute) introduction to exercising at home. Your packet of materials will include a DVD, a booklet that shows you how to exercise after your transplant and a log to help you keep track of your activity. We will also give you an electronic step counter to help you track how much you walk for exercise.

  As part of the study, we may ask you to walk for exercise at a time and location of your choice as often as 3 to 5 times a week for up to 20-30 minutes each time.
- **Group 3 - Stress Management**
  If you are assigned to the stress management group, in addition to the general information DVD you will get a packet of materials along with a short (10 minute) introduction to stress management. Your packet will include a DVD, compact disc (CD), a booklet

which shows you different ways to better manage stress after your transplant, and a log to help you track the methods you use.

As part of the study, we may ask you to use stress management techniques such as paced abdominal breathing, progressive muscle relaxation with guided imagery, and use of coping self-statements to decrease stress.

- **Group 4 - Exercise and Stress Management**
  If you are assigned to the group that combines exercise and stress management, in addition to the general information DVD you will get a packet of materials along with a short (15 minute) introduction to exercise and stress management. Your packet will include a DVD, and compact disc (CD), a booklet about exercise and stress management, a log to help you track your exercise and stress management activities, and an electronic step counter.

  As part of the study, we may ask you to walk for exercise at a time and location of your choice as often as 3 to 5 times a week for up to 20-30 minutes each time.

  We may also ask you to use stress management techniques such as paced abdominal breathing, progressive muscle relaxation with guided imagery, and use of coping self-statements to decrease stress.

Scheduled Study Visits or Phone Contacts

A study visit or telephone contact is a meeting that you have with the person in charge of the study or another member of the research team. You will need to have five (5) study visits or contacts over six months. Your enrollment visit will be done in person. The remaining follow-up visits for this study may be done in person or by phone.

Study Visits or Contacts

1. Enrollment, any time between 6 weeks and one day before transplant – up to 40 minutes (if you enrolled more than two weeks before your transplant, you will also get an extra reminder call before your transplant). At the enrollment visit you will complete baseline questionnaires (approximately 20 minutes), receive your materials, and may receive training based on your group assignment (approximately 10-20 minutes)
2. One (1) month after transplant - 10 minutes. You will talk with a member of the study team and complete questionnaires (5 minutes).
3. Two (2) months - 10 minutes. You will talk with a member of the study team and complete questionnaires (5 minutes).
4. Three (3) months (100 days) - 15 minutes. You will complete questionnaires (15 minutes).
5. Six (6) months - 15 minutes. You will complete questionnaires (15 minutes).

Your total length of study participation will last 6 months.

Study Evaluations

Your study enrollment session and every follow-up visit will include several surveys for you to complete that may be on paper or asked by the study staff. The surveys will help us evaluate the different activities of each group at the end of the study. All of the in-person visits will happen during your regularly scheduled appointments.

The surveys for this study will ask questions about:

- Your physical and emotional health
- How often and how long you have exercised between visits and contacts
- The number of times you may have used certain methods to manage stress between visits and contacts

Additional Evaluations and Procedures

During the study, some of the research staff's contacts with participants will be recorded on audio tape. The purpose of this recording is to make sure that the research team members continue to carry out the research procedures correctly. You will be asked for permission before any audio recording of your contact with research staff.

5. Alternative Treatments

If you choose to not join or you decide to leave this study, your regular medical care will not be affected in any way. Whether or not you join this study, you will receive the usual physical and emotional care given to transplant patients at your transplant center.

Physical and emotional care choices may include:

- Meeting with a nurse or social worker.
- Attending patient support groups to help you with the stress and side effects of your treatment.

Please talk with your doctor about other options. Every treatment option has benefits and risks. Your study doctor will discuss these options with you. If you decide not to participate in this research study, your medical care will not be affected in any way.

6. Risks and Discomforts

Small but possible risks for this current study are primarily related to exercise. The chances that these things might happen to you are considered to be small because you will be screened for any existing health conditions (for example, heart or lung disease) as part of your evaluation prior to transplantation that would make it unsafe for you to exercise.

Possible risks from exercise include:

- Shortness of breath (dyspnea)
- Muscle or joint sprains (musculoskeletal injury)
- Foot pain or blisters
- Heat-related injury (dehydration) that might result from exercise training

Muscle tensing as part of active relaxation and deep breathing for stress management may feel uncomfortable to some people. You should not practice any stress management methods that feel painful or uncomfortable.

If you do decide to participate, we will take extra measures to limit the chances of you getting hurt. These measures include exercise plans that are a good fit for your physical condition and suggesting ways to prevent possible muscle strain and soreness as well as dehydration.

If you have any of the problems due to exercising or using the stress management methods that we have described, tell the person in charge of this study or study staff at your next visit. If these problems bother or worry you or if you have other problems, call the person in charge of this study at *[telephone number]*

New risks might appear at any time during the study that are different from the risks listed in this Consent Form. We will promptly tell you of any new information that might affect your decision to participate.

7. Possible Benefits

Taking part in this study may or may not make your health better.

Earlier studies suggest that patients who exercise or use stress management methods after transplant may experience better physical and mental well-being than patients who do not exercise or use stress management methods after transplant. Although earlier studies suggest benefits, we don't know if you will get any benefits by taking part in this study. That is why we are doing this research study. What we learn may help to improve the quality of life of other patients after transplant.

8. New Information Available During the Study

During this research study, new information about exercise or stress management methods or the risks and benefits of the study may become known to the study doctors. If this happens, they will tell you about the new information. The new information may mean that you can no longer participate in the study, or that you may not want to continue in the study.

If this happens, the study doctor will stop your participation in the study and you will be offered all available care to suit your needs and medical condition.

9. Privacy, Confidentiality and Use of Information

Your confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy.

Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Your study number is not related to your name, social security number or medical record number at [insert facility name].

Information about your transplant from your original medical records may be seen or sent to national and international transplant registries, including:

- The Center for International Blood and Marrow Transplant Research (CIBMTR)
- The National Marrow Donor Program (NMDP)
- The Food and Drug Administration (FDA)
- The National Institutes of Health (NIH), which include the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI)
- Data Coordinating Center of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN)
- Other authorized study organizations
- We will not identify you by name in any publications or reports that come from these organizations or groups.

10. Ending Your Participation

The study doctor or the study sponsor may stop the study at any time. We may ask you to leave the study if you do not follow directions or if you suffer from side effects of the treatment. If you are asked to leave the study, the reasons will be discussed with you.

Possible reasons to end your participation in this study include:

- You do not meet the study requirements.
- The study doctor decides that it would be harmful to you to stay in the study.
- You are having serious side effects.
- You cannot keep appointments.
- The study is stopped for any reason.

11. Physical Injury as a Result of Participation

It is important that you tell the doctor responsible for this study if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at _____ *[telephone number]*.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

In case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

12. Compensation or Payment

You will not be paid for your participation in the research study. You will not get compensation or reimbursement for any extra expenses (travel, meals, etc.) you may have through your participation on this trial.

13. Costs & Reimbursements

You and/or your health plan/insurance company will need to pay for all of the costs of treating your cancer. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment. However, participation in this study does not require any additional medical tests, evaluations or procedures so we do not anticipate that participation in this study will cost more than routine care.

All costs of your care will need to be paid by you and/or your health plan/insurance company.

The companies that make the materials used in this study did not plan or design this clinical trial. They will also not have a part in analyzing the results of this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask for your free copy.

14. Ethical Review

The ethical aspects of this research study have been reviewed and approved by [name of IRB].

15. Further Information

If you need any information about this study, or if you have any problems while you are participating in this study you can contact the study doctor or his/her staff. They may be contacted at the telephone numbers listed here.

[Insert name and contact details]

16. Independent Contact

If you wish to speak to someone not directly involved in the study, or if you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

[Insert appropriate contact details]

Health Insurance Portability and Accountability Act 1 (HIPAA1) Authorization to use and disclose individual health information for research purposes

A. Purpose

As a research participant, I authorize the Principal Investigators and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research study:

A Phase III Randomized, Multi-center Trial Testing Whether Exercise or Stress Management Improves Functional Status and Symptoms of Autologous and Allogeneic Recipients.

B. Individual Health Information to be Used or Disclosed

My individual health information that may be used or disclosed to do this research includes:

- Demographic information (for example: date of birth, sex, weight).
- Medical history (for example: diagnosis, complications with prior treatment).
- Findings from physical exams.
- Laboratory test results obtained at the time of work up and after treatment (for example: blood tests, biopsy results).

C. Parties Who May Disclose My Individual Health Information

The researcher and the researcher's staff may collect my individual health information from:

(List hospitals, clinics or providers from which health care information can be requested).

D. Parties Who May Receive or Use My Individual Health Information

The individual health information disclosed by parties listed in item c and information disclosed by me during the course of the research may be received and used by the following parties:

- Principal Investigators
  - Stephanie J. Lee, M.D., M.P.H, Co-Investigator
  - Paul B. Jacobsen, Ph.D., Co-Investigator
- Members of the BMT CTN Data and Coordinating Center and 0902 Protocol Team
- The Center for International Blood and Marrow Transplant Research (CIBMTR) and the National Marrow Donor Program (NMDP)
- National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI), both of the National Institutes of Health (NIH), study sponsors
- U.S. government agencies that are responsible for overseeing research such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP)
- U.S. government agencies that are responsible for overseeing public health concerns such as the Centers for Disease Control (CDC) and federal, state and local health departments

[1] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information

- Other:_____

_____

E. Right to Refuse to Sign this Authorization

I do not have to sign this Authorization. If I decide not to sign the Authorization, I will not be allowed to participate in this study or receive any treatment related to research that is provided through the study. My decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

F. Right to Revoke

I can change my mind and withdraw this authorization at any time by sending a written notice to the Principal Investigator to inform the researcher of my decision. If I withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

G. Potential for Re-disclosure

My individual health information disclosed under this authorization may be subject to re-disclosure outside the research study and no longer protected. Examples include potential disclosures for law enforcement purposes, mandated reporting or abuse or neglect, judicial proceedings, health oversight activities and public health measures.

H. This authorization does not have an expiration date.

TITLE:
A Phase III Randomized, Multi-center Trial Testing Whether Exercise or Stress Management Improves Functional Status and Symptoms of Autologous and Allogeneic Recipients.

PROTOCOL NUMBER:
0902

INVESTIGATORS:
Stephanie J. Lee, M.D., M.P.H, Co-Investigator
Paul B. Jacobsen, Ph.D., Co-Investigator

Participant Name	Date
Signature	Date

I certify that I have provided a verbal explanation of the details of the research study, including the procedures and risks. I believe the participant has understood the information provided.

Signature	Date
Signature of Counseling Physician	Date