23-008130

# Mates in Motion: Feasibility and Acceptability of a Couple-Based Physical Activity Intervention

NCT06073951

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Name and Clinic Number

**Approval Date:** **July 22, 2025**
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# RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

**Study Title:** Mates in Motion: Feasibility and Acceptability of a Couple-Based Physical Activity Intervention - **Patient**

**IRB#:** 23-008130

**Principal Investigator:** Nandita Khera, MD and Colleagues

## Key Study Information

| | |
|---|---|
| This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered. | |
| **It's Your Choice** | This is a research study. Being in this research study is your choice. You do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part. |
| **Research Purpose** | You have been asked to take part in this research because you are scheduled to receive a hematopoietic cell transplant or chimeric antigen receptor T-cell therapy (CART) at Mayo Clinic Arizona Cancer Center. These treatments can cause side effects such as fatigue, which in turn can lead to decreases in physical activity. They can also be challenging for caregiving partners or spouses. The purpose of this research is to see if a program for couples coping with transplant or CART can help increase physical activity among both patients *and* partners. |
| **What's Involved** | Study participation involves 3 major activities:<br>(1) Completing questionnaires twice, once before transplant and once again approximately 100 days after transplant or CART.<br>(2) Completing a test of physical endurance twice, once before transplant and once again approximately 100 days after transplant or CART. This involves walking for 2 minutes. |

| | |
|---|---|
| | (3) Wearing a study-provided physical activity tracker on your wrist.<br>Based on random assignment (like flipping a coin), the study also involves either participating in a program called *Mates in Motion* with your spouse/ partner or <u>not</u> participating in the program.<br><br>The *Mates in Motion* program focuses on walking. Each week you will be given a step goal, the number of steps to try to take each day. This will be based on how many steps you took the previous week (measured by the wrist-worn tracker) and will not exceed your second-highest day the week prior. Your spouse/partner will be given their own step goal. In meetings with a health counselor, you will discuss ways to support one another in increasing steps.<br><br>The total time for participation in the study is almost 4 months. |
| **Key Information** | As with all research, there is a chance that confidentiality could be compromised. However, we take precautions to minimize this risk.<br><br>We do not foresee any research-related injuries occurring during your participation. We have built in checks to make sure that participants are approved for a walking program by their provider.<br><br>There is no cost to you or your partner to participate in this study. This study is being done to gather information, to see if our program is feasible and acceptable, and to see if it increases physical activity. You may choose not to take part. |
| **Learn More** | If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us. |

## Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

## Contact Information

| If you have questions about … | You can contact … |
|---|---|
| ▪ Study tests and procedures<br>▪ Materials you receive<br>▪ Research-related appointments<br>▪ Research-related concern or complaint<br>▪ Research-related injuries or emergencies<br>▪ Withdrawing from the research study | **Principal Investigator:** Nandita Khera, MD<br>**Phone:** (480) 342-3047<br><br>**Institution Name and Address:**<br>Mayo Clinic Arizona<br>5777 E. Mayo Blvd<br>Phoenix, AZ 85054<br><br>**Cancer Clinical Trials Referral Office (contact for all Mayo locations):**<br>(507) 293-6386 |
| ▪ Rights of a research participant | **Mayo Clinic Institutional Review Board (IRB)**<br>**Phone:** (507) 266-4000<br>**Toll-Free:** (866) 273-4681 |
| ▪ Rights of a research participant<br>▪ Any research-related concern or complaint<br>▪ Use of your Protected Health Information<br>▪ Stopping your authorization to use your Protected Health Information<br>▪ Withdrawing from the research study | **Research Participant Advocate (RPA)**<br>**(The RPA is independent of the Study Team)**<br>**Phone:** (507) 266-9372<br>**Toll-Free:** (866) 273-4681<br><br>**E-mail:** researchparticipantadvocate@mayo.edu |
| ▪ Billing or insurance related to this research study | **Patient Account Services**<br>**Toll-Free:** (844) 217-9591 |

**Other Information:**
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.

## Why are you being asked to take part in this research study?

You are being asked to take part in this research because you are scheduled to receive a hematopoietic cell transplant or chimeric antigen receptor T-cell (CART) therapy at Mayo Clinic Arizona Cancer Center.

We plan to include 50 couples (50 hematopoietic cell transplant or CART recipients and 50 spouses/ partners) in this study.

## Why is this research study being done?

We are doing this study to test a program designed to help people undergoing hematopoietic cell transplantation or chimeric antigen receptor T cell therapy and their caregiving partners be more physically active. Couples will be randomly assigned to either the program (called Mates in Motion) or a control group. We will compare the two groups.

## Information you should know

**Who is Funding the Study?**

This study is being funded by the National Cancer Institute within the National Institutes of Health.

**Information Regarding Conflict of Interest:**

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

## How long will you be in this research study?

Participation will last almost 4 months, from before the transplant or CART to approximately 100 days after.

## What will happen to you while you are in this research study?

If you choose to participate, we will extract (pull) some of your medical record data for the study, to describe the sample and to make sure you are eligible for the study. For transplant patients, this includes type of transplant, disease for which the transplant was indicated, conditioning regimen (e.g., myeloablative), stem cell source (e.g., peripheral blood), and transplant date. We will also look periodically at platelet counts to ensure continued safety in the walking program. For CART patients, this includes disease for which CART was indicated and response to CART.

In addition, you and your spouse/partner will be asked to do each of the following activities twice, once before the transplant (baseline) and again approximately 100 days after the transplant or CART (follow-up):

- Complete a brief set of questionnaires. The questions ask about your demographic characteristics (baseline only), your physical health (both times), and your relationship with your partner (both times). This is done online and should take about 10 minutes.

- Complete a measure of physical endurance, the "2-minute walk test". This is done in the clinic. A member of our research team will mark off a 100-foot area and ask you to walk back and forth there for 2 minutes. They will measure the distance that you covered. It's okay if you need to stop during the test or end early. You will also wear a pedometer on your waist during the test, to measure the number of steps taken. If you are not able to get to the clinic for the follow-up test, we will mail you a pedometer and specific instructions to repeat the test at home.

- Wear on your wrist a study-provided device to track your physical activity. This wrist-worn device is called an ActiGraph. It is designed for research.

Those randomly assigned (by chance) to the *Mates in Motion* program will be asked to wear a different device, a Garmin vivosmart 5, during the 8-week program. This is in addition to the device wear described above, though at different times.

The Garmin is lighter and sleeker than the ActiGraph and will allow you to easily monitor your own step counts during the program. The Garmin will be yours to keep after the program. Those randomly assigned (by chance) to the control condition will also receive a Garmin to keep but this will happen at the end of the study, after the second set of measures around day 100 post-transplant or post-CART.

In addition to wearing the Garmin during the program, those randomly assigned (by chance) to the *Mates in Motion* program will meet together as a couple with a health counselor to discuss ways to increase physical activity (steps per day):

- Once per week for 8 weeks, starting approximately 30 days after transplant
- Sessions 1-4 will not exceed one hour
- Sessions 5-8 will be shorter (about 30 minutes each), to check in

During the meetings, you will share, to the extent that you are comfortable doing so, your thoughts and feelings about your physical activity and that of your partner. You will also discuss ways to communicate effectively about increasing physical activity and to support one another in this process. These strategies will focus on physical activity but can be applied to virtually any topic. In addition, the health counselor will provide support for your physical activity and offer suggestions for ways to increase and maintain walking.

All sessions with the health counselor will take place by videoconference and will be audio-recorded only. Meetings are by videoconference for convenience and for infection control following transplant. The audio-recordings will be kept confidential. Audio-recordings of the intervention sessions will be shared with the Arizona State University Principal Investigator who will supervise the health counselor, and destroyed within three years of data collection.

Each week you will be given a personalized walking goal, the number of steps to try to take per day. This will be based on the number of steps per day you took the week prior, and will not exceed your second-highest step count during that week. Each goal will thus be realistic. Your partner will be given their own goal, based on what they did the week prior.

Those randomly assigned (by chance) to the control condition will not participate in the *Mates in Motion* program. They will receive transplant care as usual. As noted above, they will also receive a Garmin device after the study.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

## What are the possible risks or discomforts from being in this research study?

You may feel an invasion of privacy in being asked to:

- Answer questions about your physical activity and your relationship with your partner on the questionnaires
- Discuss your physical activity and your partner's physical activity during sessions with a health counselor (if randomly assigned to participate in the Mates in Motion program)
- Wear a device which measures your physical activity

You may skip any question you do not wish to answer. During study sessions, you are in control of what you choose to talk about, and may take breaks or stop talking altogether.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. All study data will be coded with a unique identification number, not your name or your partner's name, or any other personally identifying information. Your responses to the survey questions will be kept confidential and stored on password-protected servers.

Risk of injury is low because the program is focused entirely on walking. We will advise you to cease physical activity immediately and seek medical attention if you experience chest pain, dizziness or shortness of breath while walking. If you receive or are told that you need to receive a platelet transfusion, the Principal Investigator (Dr. Nandita Khera), will review your medical case and consult with your transplant provider to make sure that a walking program is still safe.

## Are there reasons you might leave this research study early?

You may decide to stop at any time and for any reason. You should tell the Principal Investigator if you decide to stop.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time if discovered that you do not meet criteria to participate in this study.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected. However, information already collected about you in the study may continue to be used.

## What if you are injured from your participation in this research study?

**Where to get help:**
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

**Who will pay for the treatment of research related injuries?**
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

## What are the possible benefits from being in this research study?

The study is being done for research. You and others may benefit in the future from what we learn in this research study.

The Mates in Motion program is designed to help you and your partner be physically active during the transplant recovery period and beyond. To do this, we set personalized step goals. We also give couples skills to communicate effectively about increasing physical activity, and to support one another in this process. These communication skills are transferable to discussions about other goals, decisions, and problems.

We cannot guarantee that the study or participation in the Mates in Motion program will help you or your partner personally. What we learn from the study will inform testing of the program for other hematopoietic cell transplant/ CART recipients and caregiving partners. Because physical activity has been linked to better transplant recovery and is known to alleviate stress, this program could help future patients and caregivers.

## What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information, to see if the program is feasible. You may choose not to take part in this study.

There is no formal program designed to increase physical activity that involves both patients and caregivers. Your providers will urge you to get out of bed and walk during hospitalization for transplant and beyond. You may also be referred to physical therapy, based on your medical status.

## What tests or procedures will you need to pay for if you take part in this research study?

There is no cost to you or your caregiving partner to participate in this study. Procedures include questionnaires, videoconference sessions with a health counselor, and wearing a physical activity tracker. However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

**If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.**

## Will you be paid for taking part in this research study?

Participants will not be paid for taking part in this research study. However, as noted previously, you will get a Garmin wearable device to keep and use to monitor your physical activity after the study if so desired.

## Will your information or samples be used for future research?

Your information and the data collected as part of the study will not be used or distributed for future research studies even if the identifiable information such as your name or Mayo Clinic number is removed.

## How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information during internal auditing procedures include representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects). However, these individuals are required to keep all information confidential.

To protect for the risk of loss of confidentiality, all data will be coded with an assigned identification number, which will be used in all data tabulation and subsequent publication. The list linking this number to your identity will be maintained in a password-protected data file. Only authorized study personnel from Mayo Clinic and Arizona State University will have access to this list.

Data from the study will be kept in a password-protected database on an encrypted server at Arizona State University. Only study personnel will have access to the data. These personnel will complete annual training for human subject protection and health information confidentiality. All hard copies of any research records will be placed in a locked filing cabinet within a locked Mayo Clinic or Arizona State University office. This information will not be released to anyone without your authorization.

During this research, information about your health will be collected. Under Federal Law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so.

**Approval Date:** **July 22, 2025**
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Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

### Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

### Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

### Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Arizona State University research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

### How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

Your direct contact information will be shared with Arizona State University research staff involved in this study. This is necessary for them to contact you and connect with you for program sessions, and to follow up with you during the study. After your participation in the study is complete, your information will be discarded.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

### Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

## Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

MAYO CLINIC

Name and Clinic Number

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Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

Arizona State University will store your data for a maximum of 7 years.

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## Enrollment and Permission Signatures

**Your signature documents your permission to take part in this research.**

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

**Person Obtaining Consent**

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

MAYO CLINIC

Name and Clinic Number

**Approval Date:** **July 22, 2025**
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# RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

**Study Title:** Mates in Motion: Feasibility and Acceptability of a Couple-Based Physical Activity Intervention - **Caregiver**

**IRB#:** 23-008130

**Principal Investigator:** Nandita Khera, MD and Colleagues

## Key Study Information

| This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered. | |
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| **It's Your Choice** | This is a research study. Being in this research study is your choice. You do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part. |
| **Research Purpose** | You have been asked to take part in this research because your spouse/partner is scheduled to receive a hematopoietic cell transplant or a chimeric antigen receptor T-cell (CART) therapy at Mayo Clinic Arizona Cancer Center. These treatments can cause side effects such as fatigue, which in turn can lead to decreases in physical activity. Theycan also be challenging for caregiving partners or spouses. The purpose of this research is to see if a program for couples coping with transplant or CART can help increase physical activity among both patients *and* partners. |
| **What's Involved** | Study participation involves 3 major activities:<br>(1) Completing questionnaires twice, once before your spouse's/ partner's transplant and once again approximately 100 days after their transplant or CART. |

| | |
|---|---|
| | (2) Completing a test of physical endurance twice, once before the transplant and once again approximately 100 days after the transplant or CART. This involves walking for 2 minutes.<br>(3) Wearing a study-provided physical activity tracker on your wrist.<br><br>Based on random assignment (like flipping a coin), the study also involves either participating in a program called *Mates in Motion* with your spouse/ partner or <u>not</u> participating in the program.<br><br>The *Mates in Motion* program focuses on walking. Each week you will be given a step goal, the number of steps to try to take each day. This will be based on how many steps you took the previous week (measured by the wrist-worn tracker) and will not exceed your second-highest day the week prior. Your spouse/partner will be given their own step goal. In meetings with a health counselor, you will discuss ways to support one another in increasing steps.<br><br>The total time for participation in the study is almost 4 months. |
| **Key Information** | As with all research, there is a chance that confidentiality could be compromised. However, we take precautions to minimize this risk.<br><br>We do not foresee any research-related injuries occurring during your participation.<br><br>There is no cost to you or your partner to participate in this study. This study is being done to gather information, to see if our program is feasible and acceptable, and to see if it increases physical activity. You may choose not to take part. |
| **Learn More** | If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us. |

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If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

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| ▪ Study tests and procedures<br>▪ Materials you receive<br>▪ Research-related appointments<br>▪ Research-related concern or complaint<br>▪ Research-related injuries or emergencies<br>▪ Withdrawing from the research study | **Principal Investigator:** Nandita Khera, MD<br>**Phone:** (480) 342-3047<br><br>**Institution Name and Address:**<br>Mayo Clinic Arizona<br>5777 E. Mayo Blvd<br>Phoenix, AZ 85054<br><br>**Cancer Clinical Trials Referral Office (contact for all Mayo locations):**<br>(507) 293-6386 |
| ▪ Rights of a research participant | **Mayo Clinic Institutional Review Board (IRB)**<br>**Phone:** (507) 266-4000<br>**Toll-Free:** (866) 273-4681 |
| ▪ Rights of a research participant<br>▪ Any research-related concern or complaint<br>▪ Use of your Protected Health Information<br>▪ Stopping your authorization to use your Protected Health Information<br>▪ Withdrawing from the research study | **Research Participant Advocate (RPA)**<br>**(The RPA is independent of the Study Team)**<br>**Phone:** (507) 266-9372<br>**Toll-Free:** (866) 273-4681<br><br>**E-mail:** researchparticipantadvocate@mayo.edu |
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**Other Information:**
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.

## Why are you being asked to take part in this research study?

You are being asked to take part in this research because your partner/spouse is scheduled to receive a hematopoietic cell transplant or chimeric antigen receptor t-cell (CART) therapy at Mayo Clinic Arizona Cancer Center.

We plan to include 50 couples (50 hematopoietic cell transplant or CART recipients and 50 spouses/ partners) in this study.

## Why is this research study being done?

We are doing this study to test a program designed to help people undergoing hematopoietic cell transplantation or CART and their caregiving partners be more physically active. Couples will be randomly assigned to either the program (called *Mates in Motion*) or a control group. We will compare the two groups.

## Information you should know

**Who is Funding the Study?**

This study is being funded by the National Cancer Institute within the National Institutes of Health.

**Information Regarding Conflict of Interest:**

Your partner's healthcare provider may be referring them to this research study, and you by association given your connection to the transplant or CART process as a caregiving spouse/ partner. If their healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, their healthcare provider will be happy to refer them to another investigator on the research study team for them (and you) to decide if you want to participate in the study.

## How long will you be in this research study?

Participation will last almost 4 months, from before the transplant or CART to approximately 100 days after the transplant.

## What will happen to you while you are in this research study?

If you choose to participate, you and your spouse/partner will be asked to do each of the following activities twice, once before the transplant or CART therapy (baseline) and again approximately 100 days after(follow-up):

- Complete a brief set of questionnaires. The questions ask about your demographic characteristics (baseline only), your physical health (both times), and your relationship with your partner (both times). This is done online and should take about 10 minutes.

- Complete a measure of physical endurance, the "2-minute walk test". This is done in the clinic. A member of our research team will mark off a 100-foot area and ask you to walk back and forth there for 2 minutes. They will measure the distance that you covered. It's okay if you need to stop during the test or end early. You will also wear a pedometer on your waist during the test, to measure the number of steps taken. If you are not able to get to the clinic for the follow-up test, we will mail you a pedometer and specific instructions to repeat the test at home.

- Wear on your wrist a study-provided device to track your physical activity. This wrist-worn device is called an ActiGraph. It is designed for research.

Those randomly assigned (by chance) to the *Mates in Motion* program will be asked to wear a different device, a Garmin vivosmart 5, during the 8-week program. This is in addition to the device wear described above. The Garmin is lighter and sleeker than the ActiGraph and will allow you to easily monitor your own step counts during the program. The Garmin will be yours to keep after the program. Those randomly assigned (by chance) to the control condition will also receive a Garmin to keep but this will happen at the end of the study, after the second set of measures around day 100 post-transplant or post-CART.

In addition to wearing the Garmin during the program, those randomly assigned (by chance) to the *Mates in Motion* program will meet together as a couple with a health counselor to discuss ways to increase physical activity (steps per day):

- Once per week for 8 weeks, starting approximately 30 days after transplant or CART
- Sessions 1-4 will not exceed one hour
- Sessions 5-8 will be shorter (about 30 minutes each), to check in

During the meetings, you will share, to the extent that you are comfortable doing so, your thoughts and feelings about your physical activity and that of your partner. You will also discuss ways to communicate effectively about increasing physical activity and to support one another in this process. These strategies will focus on physical activity but can be applied to virtually any topic. In addition, the health counselor will provide support for your physical activity and offer suggestions for ways to increase and maintain walking.

All sessions with the health counselor will take place by videoconference and will be audio-recorded only. Meetings are by videoconference for convenience and for infection control following transplant. The audio-recordings will be kept confidential. Audio-recordings of the intervention sessions will be shared with the Arizona State University Principal Investigator who will supervise the health counselor and destroyed within three years of data collection.

Each week you will be given a personalized walking goal, the number of steps to try to take per day. This will be based on the number of steps per day you took the week prior and will not exceed your second-highest step count during that week. Each goal will thus be realistic. Your partner will be given their own goal, based on what they did the week prior.

Those randomly assigned (by chance) to the control condition will not participate in the *Mates in Motion* program. They will receive transplant care as usual. As noted above, they will also receive a Garmin after the study.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

## What are the possible risks or discomforts from being in this research study?

You may feel an invasion of privacy in being asked to:

- Answer questions about your physical activity and your relationship with your partner on the questionnaires

- Discuss your physical activity and your partner's physical activity during sessions with a health counselor (if randomly assigned to participate in the *Mates in Motion* program)
- Wear a device which measures your physical activity

You may skip any question you do not wish to answer. During study sessions, you are in control of what you choose to talk about and may take breaks or stop talking altogether.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk. All study data will be coded with a unique identification number, not your name or your partner's name, or any other personally identifying information. Your responses to the survey questions will be kept confidential and stored on password-protected servers.

Risk of injury is low because the program is focused entirely on walking. We will advise you to cease physical activity immediately and seek medical attention if you experience chest pain, dizziness or shortness of breath while walking.

## Are there reasons you might leave this research study early?

You may decide to stop at any time and for any reason. You should tell the Principal Investigator if you decide to stop.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time if discovered that you do not meet criteria to participate in this study.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected. However, information already collected about you in the study may continue to be used.

## What if you are injured from your participation in this research study?

**Where to get help:**
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

**Who will pay for the treatment of research related injuries?**
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

## What are the possible benefits from being in this research study?

The study is being done for research. You and others may benefit in the future from what we learn in this research study.

The *Mates in Motion* program is designed to help you and your partner be physically active during the transplant/CART recovery period and beyond. To do this, we set personalized step goals. We also give couples skills to communicate effectively about increasing physical activity, and to support one another in this process. These communication skills are transferable to discussions about other goals, decisions, and problems.

We cannot guarantee that the study or participation in the *Mates in Motion* program will help you or your partner personally. What we learn from the study will inform testing of the program for other hematopoietic cell transplant and CART recipients and their caregiving partners. Because physical activity has been linked to better recovery and is known to alleviate stress, this program could help future patients and caregivers.

## What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information, to see if the program is feasible. You may choose not to take part in this study.

There is no formal program designed to increase physical activity that involves both patients *and* caregivers.

## What tests or procedures will you need to pay for if you take part in this research study?

There is no cost to you or your caregiving partner to participate in this study. Procedures include questionnaires, videoconference sessions with a health counselor, and wearing a physical activity tracker. However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

**If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.**

## Will you be paid for taking part in this research study?

Participants will not be paid for taking part in this research study. However, as noted previously, you will get a Garmin wearable device to keep and use to monitor your physical activity after the study if so desired.

## Will your information or samples be used for future research?

Your information and the data collected as part of the study will not be used or distributed for future research studies even if the identifiable information such as your name or Mayo Clinic number is removed.

## How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy.

Organizations that may inspect and copy your information during internal auditing procedures include representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects). However, these individuals are required to keep all information confidential.

To protect for the risk of loss of confidentiality, all data will be coded with an assigned identification number, which will be used in all data tabulation and subsequent publication. The list linking this number to your identity will be maintained in a password-protected data file. Only authorized study personnel from Mayo Clinic and Arizona State University will have access to this list.

Data from the study will be kept in a password-protected database on an encrypted server at Arizona State University. Only study personnel will have access to the data. These personnel will complete annual training for human subject protection and health information confidentiality. All hard copies of any research records will be placed in a locked filing cabinet within a locked Mayo Clinic or Arizona State University office. This information will not be released to anyone without your authorization.

During this research, information about your health will be collected. Under Federal Law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

### Your health information may be collected from:

- Research procedures, including research office visits, tests, interviews and questionnaires.

### Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

### Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Arizona State University research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.

- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

## How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

Your direct contact information will be shared with Arizona State University research staff involved in this study. This is necessary for them to contact you and connect with you for program sessions, and to follow up with you during the study. After your participation in the study is complete, your information will be discarded.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

## Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private, and it may no longer be protected by the Privacy Rule.

MAYO CLINIC

Name and Clinic Number

**Approval Date:** **July 22, 2025**
**Not to be used after:** **August 19, 2025**

## Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

Arizona State University will store your data for a maximum of 7 years.

MAYO CLINIC

Name and Clinic Number

**Approval Date:** **July 22, 2025**
**Not to be used after:** **August 19, 2025**

## Enrollment and Permission Signatures

**Your signature documents your permission to take part in this research.**

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

**Person Obtaining Consent**

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature