Official Title: LCI-HEM-SCD-ST3P-UP-001: A Comparative Effectiveness Study of Peer Mentoring [PM] versus Structured Transition Education Based Intervention [STE] for the Management of Care Transitions in Emerging Adults with Sickle Cell Disease (SCD)
NCT03593395
IRB-Approved Date: 08/26/2020

ATRIUM HEALTH CONSENT TO PARTICIPATE IN A RESEARCH STUDY FOR MENTEE/PARTICIPANT

ADULT SUBJECT / PARENT / LEGAL GUARDIAN / ADOLESCENT 16-AGE OF MAJORITY / SUBJECTS WHO TURN AGE OF MAJORITY DURING THE STUDY

Sponsor / Study Title:	**Levine Cancer Institute /Comparative Effectiveness Study of Peer Mentoring [PM] versus Structured Transition Education Based Intervention [STE] for the Management of Care Transitions in Emerging Adults with Sickle Cell Disease (SCD)**
Protocol Number:	**LCI-HEM-SCD-ST3P-UP-001**
Principal Investigator: (Study Doctor)	**Padmaja Veeramreddy, M.B.B.S.**
Telephone:	[redacted]
Address:	**Levine Cancer Institute - Carolinas Medical Center** [redacted] **Torrence E. Hemby Pediatric Hematology and Oncology Center** [redacted]

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign and date your name at the end of this form. You cannot take part in this research study until you sign and date this form.

If you are the parent or legal guardian of a child who may take part in this study, your permission and the permission of your child will be needed. When "you" appears in this form, it may refer to you or your child; "we" means the study doctors and study staff.

Affix Participant Barcode Label Here

INTRODUCTION

Your study doctor and his/her study associates (the investigators) are asking you to participate in a research study. The purpose of this study is to see if young adults with Sickle Cell Disease (SCD) are better prepared and able to manage their health when moved from pediatric care to adult care if they receive a structured education-based program alone (usual care) or a structured education-based program with a peer mentor. You are being asked to take part in this study because you have SCD, are between 16 and 25 years old, and are currently receiving your care in a pediatric sickle cell clinic. This is a clinical trial, a type of research study. Your study doctor or research staff will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You have the option not to participate. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, please ask your study doctor or research staff for more explanation.

This study is being coordinated by Levine Cancer Institute (LCI). Funding for this research was provided by The Patient-Centered Outcomes Research Institute (PCORI).

WHY IS THIS STUDY BEING DONE?

This study is being done to see how well young adults with SCD do after leaving pediatric care and moving to adult care. We will compare a structured transition program with a structured transition program that includes a peer mentor to provide additional support. Every young adult in this study will be part of a structured transition program within their sickle cell clinic that is designed specifically to help young adults prepare to move to adult care. This structured program (usual care) will include regular clinic visits with their sickle cell provider, education about the differences between health care for children and adults, SCD and how it changes as you get older, how you can take better care of yourself, and ongoing assessments to determine what support each young adult needs for them to succeed. Support is then customized for each young adult based on the needs identified. Some of the young adults participating in this study will have the addition of a peer mentor. The peer mentor will be someone older with SCD or a caregiver of someone with SCD who has done well with the move from pediatric to adult care. Peer mentors will be trained and supervised to coach young adults living with SCD to become successful taking care of their health needs.

It is standard practice for clinics and programs that provide care for young adults with chronic disease to have such a structured transition program in place; however, this has not always been consistent. With this research project, the investigators have worked with your sickle cell clinic to put in place a transition program that is available to ALL young adults with SCD.

The purpose of this study is to find out if extra support provided by a peer mentor will improve the transition from pediatric to adult care for young adults with SCD. We will compare using the following outcomes:

- The number of visits to the emergency department or admissions to the hospital during the time preparing for the transition to adult care and for at least 2 years after moving to adult care
- The number of clinic appointments that are kept with medical providers during the time preparing for the transition to adult care and for at least 2 years after moving to adult care
- Reported quality of life, ability to cope, and ability to manage own health
- Reported satisfaction with the quality of care received from the medical system and the transition process
- Participant reported markers of a successful transition

This is an observational study; therefore, you will **not** receive any treatments or additional medications as part of this study.

We will collect your responses about your experience and quality of life using surveys you can take either on your electronic device or on paper. We will also collect information from your SCD provider on how many times you go to the emergency department and/or get admitted to the hospital, how long you stay in the hospital, and how often you are able to make it to your clinic appointments as scheduled. We are hoping to learn about the various challenges that young adults with SCD face during the transition period. We also hope to find out if adding a peer mentor to the structured program of support for young adults during transition provides any added benefit to their overall health and ability to receive care.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 537 young adults with SCD will take part in this study and about half will be assigned a peer mentor. There will be about 120 peer mentors in this study with each peer mentor assigned no more than three mentees. There will be about 25 advisors who each support no more than 5 peer mentors.

SCD providers taking part in this study will be randomized to either the standard transition program alone (routine care) or standard transition program plus peer mentoring. Randomization by site means that each SCD clinic is put into a group by chance, like flipping a coin, only it is done by a computer. For every SCD clinic assigned to provide a standard transition program alone, one site will be assigned to offer a standard transition program plus peer mentoring. Neither you nor your study doctor can choose the group you will be in.

Your participation in this study may last between 2 ½ to 5 years.

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HOW THE STUDY WORKS

Before you begin the study

To participate in this study, you will need to review, sign and date this consent form and provide authorization for the release of your medical records for research purposes. By doing so, you are giving us permission to determine if you are eligible to participate in this study. To determine if you are eligible, we will need to collect important information from your medical record about your demographics (for example, age) and medical history. To be eligible you must:

- Be 16 -25 years of age
- Be able to read and speak English
- Have Sickle Cell Disease
- Still be receiving care in a pediatric SCD clinic and plan to transfer to an adult program within 6-12 months
- Have access to a phone and computer with internet
- Not known to be currently pregnant

During the study

Your SCD clinic has been randomized to either receive the standard transition program alone or the standard transition program plus peer mentoring. Every young adult with SCD who receives care in your SCD clinic will be offered the SAME opportunity. All young adults with SCD at participating sites may benefit from the standard transition program (usual care). This involves special attention and planning that is done to help each young adult with SCD have a smooth path as they prepare to move on to adult care.

- **Baseline**:
    - After consenting to the study, if you choose to download the ST3P-UP application (a sickle cell education tool), the Transition Coordinator will assist you. Your provider will also have access to this application during your appointments to help you understand your health and how to take care of yourself.
    - Collection of demographics and medical history to include: date of birth, age, race, gender, sickle cell genotype, zip code of residence, presence of a sibling, parent, or child with SCD, academic achievement, disability status, marital status, employment status, living arrangement, household income, age at transfer to adult care, type of SCD adult provider (primary care versus specialty), and number of emergency department and urgent care visits and/or hospital admissions in the preceding 12 months.
    - You will be given surveys that take approximately 30 minutes to complete. These surveys will assess your quality of life, how confident you feel with your ability to take care of your health as an adult, how much support you feel you have from your social networks and how satisfied you are with the healthcare that you are receiving.

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- **ALL participants will receive the standard transition program** (usual care)
    - All participants may benefit from their SCD clinic and providers working to put in place standard procedures to help support young adults who are in the process of moving from pediatrics to adult care. Some of this support will be education provided through the ST3P-UP application or by your SCD provider during your regular appointments.
- **Every 3 months after enrollment:**
    - All participants will have a scheduled clinic visit with SCD provider
    - An education module will be shared with you in clinic.

- **Every 6 months after enrollment**:
    - You will be sent links to your phone or electronic device to complete surveys about how you are doing. You will be given instructions on how to complete these. These are the same surveys done at enrollment, and usually take about 30 minutes to complete. You also have the option to fill out paper versions of these surveys. The paper surveys will have the same questions as the surveys that you can access through your electronic device.
    - We will track the number of times you are admitted to the hospital, need to go to the emergency department, and see your SCD or primary care provider in the clinic during the study period.
- **When you complete the study:**
    - We will update any demographic or medical history changes since your enrollment to the study.
    - You will be asked to complete the same surveys done during the study, with one additional questionnaire about your satisfaction with the transition services you were provided.
    - Your access to the ST3P-UP application will be deactivated.

<u>If you are assigned to the Peer Mentoring Group:</u>

Peer mentoring will occur through a virtual platform and include structured frequent contacts between mentor and mentee for a minimum of 30 months. The platform was created by InquisitHealth™. InquisitHealth™ Mentor 1to1™is a full-service virtual mentoring platform vendor focused on improving clinical outcomes of high risk, high cost patients by connecting them to peer mentoring support that is standardized and structured without burdening resources.
If you are in the group that will receive peer mentoring, you will be notified via phone or email that you have been matched with a mentor and provided next steps to establish mentoring calls.

A peer mentor is someone who has already transitioned to adult care and can provide you with tips

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and support as you go through the process yourself. Your mentor will be at least 5 years older than you and will have completed and passed a background check that reflects no prior convictions with the exception of minor traffic violations, parking tickets, and/or any dismissals. If you have a gender preference, you will be able to indicate this below. Mentor-mentee matching will be based on your availability and that of your mentor. InquisitHealth™ will work with you to set up your first call with your mentor.

Your mentor will contact you every week for the first three months and then at least every two weeks until at least 24 months after you have transferred to adult care. You can schedule calls at a time most convenient for you and the peer mentor. Peer mentors will ask questions about goals related to being involved in your healthcare, being able to speak for yourself and navigating your healthcare, managing your condition, and taking care of yourself. Along with your peer mentor, you will discuss your health-related goals, identify a vision of your health and well-being, and develop goals and actions to progress toward that vision. Through this process, your peer mentor will help you learn how to take charge of and manage your health and make the best choices for your individual situation.

Your mentor will continue to reach out to you throughout the course of the study to see how you are progressing with reaching and keeping up with your goals.

Gender Preference Options:
Please provide your initials and gender preference below.

_____ I have a gender preference for my mentor.
Gender Preference: _____

_____ I don't have a gender preference for my mentor.

_____ My gender preference isn't available and I am willing to be matched with an available mentor.

<u>Audio recording</u>

Interactions between you and your mentor including calls, voicemails, and text messages may be recorded and analyzed to better understand how peer-to-peer mentoring can help improve health care outcomes. We will also monitor the frequency and length of phone calls made between you and the Peer Mentor during the mentoring program. Any identifying data will be on a secure database and will not be shared.

RISKS

You are not receiving any treatments or additional medications for being a part of this study.

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Some study activities can make participants feel uncomfortable, anxious, and/or emotionally fatigue which are symptoms of emotional distress. If you experience emotional distress, study activities will be paused until the issue is resolved.

Privacy Risks

If your personal health information were accidentally shared with unauthorized users, you may be at risk of loss of the privacy of your health data. Your privacy is very important to us and we will use many safety measures to protect it. However, despite all the safety measures that we will use, we cannot guarantee that your identity will never become known. This risk is minimized by protections described in the Confidentiality section below.

If you have a peer mentor, and you discuss feeling depressed or other concerning symptoms or situations, the peer mentor may share this information with the study team and/or your healthcare team.

Unknown Risks

You might experience risks or discomforts that are not listed in this form. Some risks may not be known yet. New ones could happen to you. Tell the study doctor or study staff right away if you have any problems.

WILL I BENEFIT FROM PARTICIPATING IN THIS STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that you will benefit from your SCD clinic putting in place a structured transition program that will provide self-management support for all young adults with SCD along with specific education to help you be more comfortable with going to adult care. This support will be available to you even if you decide not to participate in this study.

Information learned from this study may help other people in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Your alternative is to not participate in this study. If you decide not to be in the study, that will **not** in any way harm your relationship with your doctors or healthcare team.

Please talk to your study doctor about these and other options along with their risks and benefits. Please ask any questions you may have and take as much time as you need to make your decision.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You will not receive payment for taking part in this study.

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You and/or your health plan/insurance company will not be responsible for any study activities done solely for research purposes that would not have been done if you were not participating in 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 them to send you a free copy.

You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

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

This study is requesting that you answer questions about your health and healthcare experiences by completing surveys either on an electronic device or paper and, if you are in the assigned group, receiving the support of a peer mentor. The likelihood of injury because of participation in this study is very small. However, in the event you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You do not waive any legal rights by signing this form.

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

In the event that you are harmed as a result of your participation in this study, inform your study doctor immediately so you can access medical treatment.

To pay your medical expenses, the sponsor will need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

WHAT IF I WANT TO QUIT THE STUDY LATER ON?

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, your decision to not participate will not in any way harm your relationship with your doctors or healthcare team. You are free to stop being in the study if you change your mind after entering it. This would not harm your relationship with your doctors or healthcare team. If you choose to withdraw from the study, please notify the study doctor in writing at the address on page 1 of this consent form.

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The study doctor may choose to involuntarily withdraw you from the study for any reason.

We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by the sponsor, by Atrium Health (formerly known as Carolinas HealthCare System), InquisitHealthTM , Sickle Soft Inc. LLC, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

All information will be kept in a secure manner and computer records will be password protected. The responses to your survey questions will be saved to a password protected database. Some of these emails, and texts may contain health information that identifies you. Your information will be viewed by designated research staff by using a secured login and **not** by anyone who is not involved with your care.

As part of this study, we plan to use your self-report, your SCD clinic reports, insurance claims and billing information to understand how peer mentoring affects the medical services people in our study are using. This information will be used for study purposes only, secured for privacy, and will not be used to change or affect your health coverage in any way.

Basic information about you will be shared with your assigned peer mentor (if applicable) and your medical care team, including, but not limited to, your full name, age, gender; information about your SCD etc. Also, your personal information may be given out if required by law.

During the study, we will contact you by email and/or text. Some of these emails/texts may contain health information that identifies you. Only the study team will have access to these communications.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The study team may look at or copy your study records for research, quality assurance, data analysis, and training purposes.

AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor and the study investigator to collect, process and pass on to the sponsor organizations any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the study doctor and study staff,
- the study sponsor and/or its associated companies InquisitHealth™ and Levine Cancer Institute,
- regulatory or other governmental authorities of the United States and other countries,
- other persons authorized by the study sponsor,
- Atrium Health (formerly known as Carolinas HealthCare System) employees,
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- monitor your transition from pediatric care to adult care,
- compare and pool study results with those of other subjects in the clinical study.

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or healthcare team.
You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed; it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

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This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator and sponsor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study doctor in writing at the address and telephone number listed on the first page of this form. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

FINANCIAL DISCLOSURE

None of the doctors asking you to participate in this study has received or will receive money or other benefits for personal use from this study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00027706.

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.

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STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time
(if subject is age of majority or older)

_____
Printed Name of Research Subject

_____ ____/____/____ _____
Signature of Parent/Legal Guardian Date Time
(if subject is under age of majority)

_____
Printed Name of Parent/Legal Guardian (if subject is under age of majority)

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject or the subject's parent/legal guardian the nature and purpose of the above study. There has been an opportunity for the subject or the subject's parent/legal guardian to ask questions about this research study. I have been available to answer any questions that the subject or the subject's parent/legal guardian has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent

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ASSENT STATEMENT FOR ADOLESCENTS 16 –AGE OF MAJORITY

I have read this form. I know that this is a research study. I have been told about the risks and potential benefits of taking part in the study. I have asked all the questions I have about the study and have gotten answers to my questions. I know that I am free to quit the study at any time without any penalties or loss of benefits. I will tell the study doctor, the study staff or my parent(s)/guardian(s), if I choose to stop the study. I will be given a signed and dated copy of this form to keep.

I agree to take part in this research study.

_____ ____/____/____ _____

Signature of Subject Date Time

_____

Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING ASSENT

I have carefully explained to the subject and subject's parent/legal guardian the nature and purpose of the above study. There has been an opportunity for the subject and subject's parent/legal guardian to ask questions about this research study. I have been available to answer any questions that the subject and subject's parent/legal guardian has about this study.

_____ ____/____/____ _____

Signature of Person Explaining Assent Date Time

_____

Printed Name of Person Explaining Assent

Affix Participant Barcode Label Here