RCT: Life Care Specialist (LCS) - Pain management and prevention of substance misuse

Short study title: Life Care Specialist (LCS)

NCT Number: NCT04154384

ICF Version Date: 10/22/2021

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 500 people who are being studied, at Emory.

Why is this study being done?

This study is being done to learn more about Life Care Specialist (LCS) position and the value it provides to the patient and the healthcare setting in reducing misuse of prescriptions. Additionally, the resources required to carry it through. You are being asked to be in this research study because you have had or will be having surgery with one of our Orthopaedic surgeons.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be a part of the study, you have an equal chance of being assigned to any one of the two groups.

If you are in the control group you will complete 4 study visits.

If you are in the treatment group you will complete 7 study visits.

The researchers will ask you to answer questionnaires and participate in the management for your pain.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. To uncover the strengths and weaknesses of the Life Care Specialist position. In addition, the value it provides to the patient and healthcare setting and the resources required to carry through.

Alternatives to Joining This Study

If you decide not to enter this study, there is care available to you outside of this research study. You do not have to be in this study to be treated for your injury.

Costs
There are no costs for your participation on this study.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

Emory University and Grady Health System
Consent to be a Research Subject / HIPAA Authorization

Title: Life Care Specialist (LCS)

Principal Investigator: [redacted]

Sponsor: Christopher Wolf Crusade (CWC)

Investigator-Sponsor: [redacted]

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?
The main focus of the Christopher Wolf Crusade (CWC) is prevention through the use of a Life Care Specialist (LCS). We are working with key stakeholders in the opioid epidemic to develop an official pain management protocol, as well as conducting an introductory study for a new field of Pain Management.

The goal is to see Life Care Specialists (LCS) staffed in hospitals to focus on pain management and addiction prevention for patients. The LCS position does not currently exist in the healthcare field. Additionally, it will help provide information about the resources that are needed to carry it through.

What will I be asked to do?
If you agree to be a part of the study and are randomized to the control group you will have 4 study visits: hospital admission, 2 week, 6 week and 3 month follow-up.

If you agree to be a part of the study and are randomized to the treatment group you will have 7 study visits: hospital admission, 2 week, 6 week and 3 month follow-up. You'll also complete LCS interventions at your 2 week, 6 week and 3 month follow-ups.

You will be asked to complete questionnaires in person and/or via email that will give us information about your general health and your pain at each appointment and/or up to 1-year after your surgery. If any questions make you too uncomfortable to answer, you can skip them. Additionally, we will collect information from your hospital admission.

You will also get medication electronic monitoring (MEMS) devices which are Bluetooth enabled caps that fit on to standard medicine bottles. This will be provided to you by the pharmacy and are required to return them at your last follow-up.

The following will be collected:

- Demographics
- Comprehensive social determinants of health survey (SDOH)
- Revised Opioid Risk Tool (ORT)
- Short Form 36 Health Survey Questionnaire (SF-36)
- Pain Management Questionnaire (PMQ)
- Prescription Drug Use Questionnaire (PDUQ)
- PTSD Screener
- PROMIS: Sleep Disturbance
- PROMIS: Physical Function
- PROMIS: Pain Interference
- PROMIS: Prescription Pain Medication Misuse
- Opioid Literacy Tool (OLT)
- Patient Satisfaction Survey
- Naloxone Questionnaire
- Sleep Actigraphy
- Field notes and quotes from your statements

Who owns my study information?

If you join this study, you will be donating your study information. If you withdraw from the study, data that was already collected may be still be used for this study. Study reporting will not identify any one person.

What are the possible risks and discomforts?

There may be side effects from the study or procedures that are not known at this time. Rare but possible risks include: Breach of confidentiality; however, we will be sure to keep all of your protected health information in a password protected, encrypted database only accessible to study team members.

We are asking you to complete questionnaires asking about many social factors that may be sensitive and potentially emotionally upsetting. This includes information about your socioeconomic position, race, ethnic group, cultural context, gender, sexual orientation, alcohol and drug abuse, family and domestic abuse, social relationships, and residential and community context. The questionnaires will be completed in-person and/or over the phone or email. If any questions make you feel uncomfortable, you can skip them.

Though you will be using pain medications as prescribed, the doctors acknowledge that you are asked to quantify the consumption of a controlled substance, which may be a sensitive matter. Thus, in order to further protect your confidentiality of responses to survey questions and online survey responses will be stored as a set of numbers only, without identifying the question to which those numbers pertain. This data will be stored in an encrypted fashion on a commercial cloud server, which is password protected and only accessible by Emory research staff. The survey key linking the questions to your responses will also only be available to Emory investigators. All protected health information for this study, with the exception of a cell phone number, as it is required to send you text message survey questions, will be stored separately from the daily survey responses. Your participation in the text message survey may be stopped at any time by responding 'Stop' to a survey question.

Will I benefit directly from the study?
The goal is to introduce a Life Care Specialist (LCS) as an integral member of the clinical team, with a focus on "pain coaching" for trauma patients. The study results may be used to help others in the future.

Will I be compensated for my time and effort?
On your first visit, you will get a gift bag and a $10 gift card.

At your 2 week and 3 month follow-up, you will receive a $20 gift card.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Storing and Sharing your Information
De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your de-identified data to other researchers. If we do, we will not include any information that could identify you. If your data is labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

In general, we will not give you any individual results from the study of the data you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record
If you have been an Emory and Grady Health System patient before, then you already have an Emory and Grady Health System medical record. If you have never been an Emory and Grady Health System patient, you do not have one. An Emory and Grady Health System medical record will be made for you if an Emory and Grady Health System provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Grady Health System medical record you have now or any time during the study.

Tests and procedures done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Information related to your mental health.
- Information related to your pain management.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Christopher Wolf Crusade (CWC) is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:

- Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
- Public health agencies.
- Research monitors and reviewer.
- Accreditation agencies.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact [redacted] at [redacted].

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact [redacted] at [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory University Institutional Review Board at [redacted] or [redacted] or [redacted]

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at [redacted]

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at [redacted].

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Patient Name

_____ _____

Patient Signature (18 or older and able to consent) **Date** **Time**

We would like to contact you in the future to see if you would be interested in participating in another research study, distributing study efforts, or study related promotional materials. Answer Yes or No by initialing:

___ Yes, I agree to be contacted

___ No, I do not want to be contacted

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**