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

Record #

Title: Georgians Organized Against Lupus (GOAL) Study Cohort

Sub-Study: Women Empowered to Live with Lupus (WELL) Study

NCT Number: NCT02988661

Sub-Study Sponsor: National Institutes of Health (NIH R01MD010455)

Informed Consent Form Version Date: August 15, 2018

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Principal Investigator (WELL Sub-Study): Cristina Drenkard, MD, PhD
Division of Rheumatology

Principal Investigators (GOAL): S. Sam Lim, MD, MPH
Cristina Drenkard, MD, PhD
Division of Rheumatology

Introduction

You are invited to take part in this sub-study because you are participating in the main GOAL study.

This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in 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.

Before making your decision:

- Please carefully read this form or have it read to you.
- Please ask questions about anything that is not clear.

You can take a copy of this consent, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form, you will not give up any legal rights.

What is the purpose of this study?

The purpose of this research sub-study is to help us understand how well a self-management program works to improve health outcomes and reduce health care use in African American women with lupus. The Chronic Disease Self-Management Program (CDSMP), also known as Living Well with a chronic condition workshop, is a self-management education program that has been shown to help people with chronic conditions to take control of their health problems. The Living Well with a chronic condition workshop contributes to improved health in people with a variety of chronic conditions. This study focuses on African American women with lupus because this program has not been widely studied within this population.

What will I be asked to do?

If you agree to participate, we will ask you to attend the Living Well with a chronic condition workshop and answer questionnaires at 4 select time periods before and after the program. We will follow your progress for up to 18 months after the program has been completed. You may also be asked to participate in 2 in-person interviews.

The Living Well with a chronic condition workshop consist of 6 weekly classes of two and a half hours each one, for six weeks. A group of 10-16 people with different chronic health problems attend the classes together. Workshops are facilitated by two certified leaders, one or both of whom are non-health professionals with chronic diseases themselves. The workshop covers topics such as: 1) how to deal with problems such as frustration, fatigue, pain and isolation, 2) appropriate exercise for maintaining and improving strength,

flexibility, and endurance, 3) appropriate use of medications, 4) communicating effectively with family, friends, and health professionals, 5) nutrition, 6) decision making, and, 7) how to evaluate new treatments.
Each participant in the workshop receives a copy of the companion book, *Living a Healthy Life with Chronic Conditions,* and an audio relaxation CD, *Relaxation for Mind and Body*.

Workshops are conducted at community centers, and you can select the most convenient location.

You will be asked to complete health and behavior questionnaires at 4 time periods: (1) within 4 weeks of the start of the program; (2) 6 months after program completion; (3) 12 months after program completion; and (4) 18 months after program completion. Questionnaires may take between 20 and 40 minutes to complete.

You may be asked to share additional information through two in-person interviews conducted before and after the program. Each interview will take between 60 and 90 minutes. For your convenience, you can do these in-person interviews at the Emory or Grady campuses or your home.

What are the possible risks and discomforts?
There is very little risk in participating in this study. Some people may find answering questions frustrating. You have the right not to answer any question that makes you feel uncomfortable.

There is a small risk that someone outside of the study may find your personal information. However, we will do our best to keep your information private by keeping it in a secured area available only to those needing to access it for research purposes. Emory researchers will keep all information you provide confidential. The information will be stored in a locked office. Only researchers involved in this study will be able to access this information.

Will I benefit directly from the study?
People who took the Living Well with a chronic condition workshop, when compared to those who did not, demonstrated significant improvements in exercise, cognitive symptom management, communication with physicians, general health, health distress, fatigue, disability, and social/role activities limitations. They also spent fewer days in the hospital, and there was also a trend toward fewer outpatients visits and hospitalizations. However, it is not known whether this program will lead or not to better outcomes in people with lupus. Taking part in this study may not benefit you personally, but we may learn new things about lupus. Moreover, the information gained may help us find improved ways to manage the care of people with lupus.

Will I be compensated for my time and effort?
There are no costs to you for participating in this program. You will receive gift card compensation for research questionnaires completed during each time period: (1) before program $35; (2) 6 months after program completion $40; (3) 12 months after program completion $45; (4) 18 months after program completion $50. You will also be able to select among the following options regarding your transportation to the program site: 1) a $10 gas card; 2) a round-trip MARTA card; or 3) shuttle or taxi service for up to $30 round trip.
If you participate in the in-person interviews, you will receive $35 for the first interview and $40 for the second interview.
You will also be able to select among the following options regarding your transportation to the interview site: 1) a $10 gas card; 2) a round-trip MARTA card; or 3) shuttle or taxi service.

How will you protect my private information that you collect in this study?

Emory and Grady Health System will keep any research records that it creates private to the extent that is required to do so by law. Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents. If you agree to participate in this study, we will keep all facts about you private. We will use a study number to identify you rather than your name. We will keep files that link your name to the study number in a locked file cabinet and office. We will not disclose your information to anyone in any way that would identify you. Your name will not appear when we present this study, or publish its results.

In case of Injury

We will give you emergency care if you are injured by this research. However, Grady Health System or Emory University has not set aside funds to pay for this care or to compensate you if a mishap occurs. If you believe you have been injured by this research, you should contact Dr. Drenkard [redacted]

Withdrawal from the Study

You have the right to leave this study at any time without penalty. This decision will not affect in any way your current or future medical care. You will not lose any benefits to which you would be allowed if you refuse to participate or leave the study after giving your consent.

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 this study.

PHI that will be Used/Disclosed:

The PHI that we will use and/or disclose (share) for the 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.
- Laboratory test results.

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 use to report child abuse or abuse of elder 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 to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the study, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People that will Use and/or 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.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Grady Health System offices involved in the study administration.

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 the study team 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.

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
If you have any questions about this study, please call Charmayne Dunlop-Thomas or Dr. Drenkard at [redacted]. If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact the Emory Institutional Review Board at (404) 712-0720 or (877) 503-9797. If you are a patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

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Consent and Authorization

Please print your name and sign below if you agree to be in this 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 consent to keep.

_____
Name of Subject

_____ _____
Signature of Subject **Date Time**

_____
Name of Person Conducting Informed Consent Discussion

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