NCT05426902

Official Title: Utilizing Qualitative and Quantitative Methods to Understand a New Model of Type 1 and 2 Systemic Lupus Erythematosus (SLE)

Document Date: 12/22/2021

Duke University Health System

Consent To Participate In A Research Study
Study: Utilizing qualitative and quantitative methods to understand a new model of Type 1 and 2 SLE
Oral Informed Consent Form. Version: 1.1, 17NOV2021

Concise Summary
You are being asked to take part in a pilot implementation study of the Type 1 & 2 SLE Model into clinical care within Duke Rheumatology. You will be trained to use SLE@Duke, a set of tools to implement the Type 1 & 2 SLE Model. The training will include a dotphrase for your EMR note template, patient-reported outcome measure, and training on how to discuss Type 1 & 2 SLE. You will be asked to perform the intervention for all eligible patients over 4 weeks. Following the intervention, you will be invited to participate in a brief one-time interview with a trained interviewer from Duke University. You will be asked to share your experiences using SLE@Duke during clinic visits with lupus patients. The implementation study and interview are considered research.

Introduction and Purpose of Study

You are being asked to take part in a study called, "*Utilizing qualitative and quantitative methods to understand a new model of Type 1 and 2 SLE."* This study is being conducted with rheumatologists who treat people living with lupus.

The purpose of the study is pilot test SLE@Duke, a set of tools to implement the Type 1 & 2 SLE Model in a clinical setting, as well as to gain an in-depth understanding of your experiences using our intervention, SLE@Duke, during clinic visits with patients with systemic lupus erythematosus.

Researchers at Duke University are conducting the study. Dr. Amanda Eudy is the Principal Investigators and is responsible for the study. This study is funded by NIH NCATS Award Number 1KL2TR002554.

What is involved the study?

If you agree to participate, you will first complete a baseline survey to determine your existing experiences treating SLE patients and views on the Type 1 & 2 SLE Model. You will then will be trained to use the Type 1 & 2 SLE Model. The training will include a dotphrase for your EMR note template, patient-reported outcome measure, and training on how to discuss Type 1 & 2 SLE. You will be asked to perform the intervention for all patients with lupus over 4 weeks. At check-in, lupus patients will receive a questionnaire to be completed. This questionnaire will be utilized during clinical care.

We will send you reminders through the EMR when a lupus patient is scheduled, as well as check in with you weekly for troubleshooting. At the end of each visit, patients will be asked to complete an anonymous short survey about their visit. We will review charts of lupus patients to assess frequency of documentation and completing core intervention components. Charts will be reviewed during three

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4-week time periods: prior to intervention, during the intervention, and 3-months after the intervention.

Following the 4-week intervention period, all participating providers will be invited to participate in a one-on-one interview with a trained interviewer from Duke University. These interviews will explore acceptability of SLE@Duke, the extent to which they would continue to use SLE@Duke, resources needed to implement, practicality of using SLE@Duke, and perceived fit of using SLE@Duke within clinic infrastructure. Results from the interviews will be used to revise the way SLE@Duke is packaged and the Type 1 & 2 SLE Model is presented to rheumatologists. We will also ask you questions about yourself, such as your age and duration of practice. Each interview will last about 1 hour. We would like to record the interview. This is so we can rememberwhat you said. If you do not want to be recorded, we can take notes instead.

What are the possible benefits from being in this study?

There are no direct benefits to participants who take part in this research, although you may derive a sense of satisfaction from contributing to improving the management of patients with lupus.

What are the risks of the study?

The risks of taking part are very low. Participation in any research study involves some loss of privacy. Your personal information will be viewed by individuals involved in this research at Duke University. As with all studies, there is also a potential risk of loss of confidentiality or privacy to others outside of the research. We will do our best to make sure that information about you cannot be seen by people who are not part of this research, but we cannot guarantee total confidentiality. Your personal information may also be given out if required by law, although we do not anticipate this. We take many steps to protect your information (see below).

How will my information be kept confidential?

We will label all research documents with a code number, not your name. We will not mention your name in any reports, articles, or presentations about this study. The audio recordings from the interviewwill be stored securely and will be destroyed after we publish the study's main findings. The transcript and the demographic information you share will also be stored securely at Duke University. This information will be stored for up to six years. At that time, we will either destroy the information or remove any information that could identify you.

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What payment will I receive?

There are no costs to you for taking part in this study. You will receive $100 for your time.

What about my right to decline participation or withdraw from the study?

Taking part in this study is voluntary. You do not have to participate. If you want to participate in the interview, you can choose not to answer any questions during the interview. You may also stop taking part in the intervention or interview at any time. Choosing not to take part or deciding later to stop participating will not affect your participation in other studies at Duke.

Whom do I call if I have questions or problems?

If you have any questions about the interview, please contact Dr. Amanda Eudy by email at amanda.eudy@duke.edu or by telephone at 919-681-1811. For questions about your rights as a research participant, or to discuss problems about the research, contact the Duke Health Institutional Review Board (IRB) Office at (919) 668-5111.

Statement of oral informed consent

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions. My questions have been answered to my satisfaction. I have been told whom to contact if I have questions or problems about the research. I have read this oral informed consent form and agree to be in the study. I understand that I can withdraw at any time. I have a copy of this form."

_____ _____
Signature of Staff Obtaining Verbal Consent Date

_____
Participant ID#: