Official Title: Improving Medication Adherence in Chronic Rheumatic Diseases

NCT: NCT06018350

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Consent to Participate in a Research Study
Improving Medication Adherence for Patients with Chronic Rheumatic Diseases
Oral Informed Consent Form. Version: 1.0, 24Oct2023

Concise Summary
You are being asked to take part in a pilot study to test an adherence intervention for patients in general rheumatology clinic. You will undergo a 1-hour training to conduct the intervention. Training will discuss how to assess adherence using Surescripts data and effectively discuss adherence with patients. The training will also include a case to practice with a partner, a dotphrase for your EMR note template, a provider handout, and a patient handout. You will be asked to perform the intervention in clinic for patients chronic rheumatic diseases over 4 weeks. Following the intervention, you will complete a brief survey. The pilot study and survey are considered research.

Introduction and Purpose of the study
You are being asked to take part in a study called "Improving Medication Adherence for Patients with Chronic Rheumatic Diseases." This study is being conducted with rheumatologists who treat people living with chronic rheumatic diseases.

The purpose of the study is to pilot test an adherence intervention developed in the Duke Lupus Clinic in general rheumatology clinic with patients with chronic rheumatic diseases. Researchers will assess its feasibility, acceptability, and explore its impact on medication adherence.

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

What is involved in the study?
If you agree to participate, you will first complete an anonymous baseline survey to determine your current practices to promote adherence. You will then participate in a 1-hour training to conduct the adherence intervention. You will be compensated $150 for your time spent in training and answering surveys. The training will also include a dotphrase for your EMR note template. You will be asked to perform the intervention for all eligible patients over 4 weeks. Throughout the 4-week intervention period, we will send you regular reminders and will check in with you weekly for trouble shooting. We will ask you to complete a short anonymous survey about your experience with the intervention at the end of the 4 weeks.

At the end of each visit, we will ask up to 30 of your patients to complete a short, anonymous survey about their visit. We will randomly review 10 charts per provider to assess the frequency of documentation about completing core intervention components.

At 3 and 6 months after the 4-week intervention period, we will examine change in medication adherence among your patients with chronic rheumatic diseases who were seen during the intervention period. Medication adherence will be evaluated by directly pulling pharmacy refill data from Epic.

What are the possible benefits from being in the study?
The intervention training can help improve medication adherence discussions with your patients and potentially their adherence level, which in turn may help improve patient care and clinician satisfaction.

What are the risks of the study?
The risks of taking part are very low. Participation in any research study involves some potential 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 survey and demographic information you share will 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.

What payment will I receive?
You will be compensated $150 for your time spent in training and answering surveys.

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. You may stop taking part in the intervention 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. Kai Sun by email at [redacted] For questions about your rights as a research participant, or to discuss problems with 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#: