Official Study Title: Whole Health Empowerment for Endotypes of Lupus: Improving Quality of Life in SLE (WHEEL)

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Form
M0345

Duke University Health System

Consent to Participate in a Research Study
ADULT
Whole Health Empowerment for Endotypes of Lupus (WHEEL)

KEY INFORMATION SUMMARY

This research study will assess a newly developed online, peer-support program for people living with lupus. This WHEEL Program will be facilitated by certified health coaches and will offer lupus information, self-management skills, community support, and resources.

We are asking you to participate because you are living with lupus and are in the Duke Lupus Registry. If you agree to participate, you will be enrolled in the study for up to 10 months. You will attend the 11-session online Program with up to 7 other participants by teleconference every other week for up to 5 months. You will also complete 3 surveys about the program and your health. There are no physical risks associated with this study. The benefits include enjoying the program and contributing to expanding the program to others living with lupus in the community. There is, however, the potential risk of loss of confidentiality.

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Jennifer Rogers will conduct the study. The study is funded by a grant from the Department of Defense. Portions of Dr. Rogers and their research team’s salaries will be paid by this grant.

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Why is this study being done?

The purpose of this study is to study an online support and empowerment program to improve pain and fatigue for people living with lupus.

Up to 40 people will take part in this study at Duke.

What is involved in the study?

- You will be randomized to either start the online program within a month of signing up or up to 5 months after enrolling.
- Participate in 11 online sessions up to 90 minutes long for up to 5 months. Topics include learning about lupus, stress and the mind-body connection, medication and non-medication therapy, rest and sleep, movement, and improving relationships.
    - Eight small group sessions including up to 8 people with lupus, occurring every 2 weeks. Sessions will last approximately 75-90 minutes.
    - Three individual sessions with a health coach for up to 60 minutes per session.
    - Up to 2 health coaches will be facilitating the program. Other research staff may attend for program quality and improvement purposes but will not be participating in any way.
    - Sessions will be recorded and viewed for quality improvement purposes only.
- Complete 3 online surveys that include questions about your health and ask for program feedback at enrollment and after you complete the online program. You will complete one more survey up to 5 months before or after the program depending on which group you are assigned.
    - The health coaches will review your survey responses to prepare for your personalized goal-setting meetings.
- Your Duke rheumatologist will complete a brief form summarizing how they think you may benefit from the program. The form will be shared with the health coaches before the Program starts. The rheumatologist may receive updates during and/or after the Program to help better support you on your lupus journey.
- After completing the Program, you may be invited to participate in a one-on-one interview with study staff to provide feedback about your experience in the program. The interview will last about 60 minutes. These interviews will be transcribed for analysis purposes

- We will look at lupus-related data in your medical record to compare your pre-program and post-program experiences living with lupus.

You have the option for us to send you automated text messages throughout this study. You will also have the option to receive payment updates by SMS text notification. For study activities, we use a web-based system, called Twilio, which uses your phone number to send you messages. We plan to use this feature to send you text messages for reminders and surveys. As long as you agree and are a member of the study, we will contact you this way approximately 20 times during the study. If you change your mind about the messages or if your contact phone number changes, please email the study team. Because these messages are one-way only, you cannot reply or use texting to contact the study team. If you have questions or concerns about information in a message, contact your study team.

How long will I be in this study?

You will participate in the study for up to 10 months. You will attend the 11-session online program for up to 5 months. If you choose to participate in the interview, the interview may occur within 2 months after your online program ends.

You can stop participating at any time without penalty. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

What are the risks of the study?

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any questions, and you may take a break at any time during the study. *You may stop your participation in this study at any time.*

Are there benefits to taking part in the study?

If you agree to take part in this study, you may benefit from the strategies you learn in the program. We hope that the information learned from this study will benefit other people with your condition.

Will my information be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. The online sessions will take place in a group setting. There is some risk of lost confidentiality in any group setting. You will not be asked to share any personal information with the group that you do not want to share, and guidelines for confidentiality will be presented at the beginning of the focus group. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of any study-related tests or procedures may be shared with the Department of Defense and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

- representatives and affiliates of the Department of Defense
- the Duke University Health System Institutional Review Board,

If any of these groups review your research record, they may also need to review your entire medical record.

Your medical records will be accessed for up to 1 year after your program participation for lupus-related clinical visits. Your records will not be accessed after the study ends.

The interviews will be recorded and transcribed for review by a vetted transcription service. The transcript will not include information, such as your name. All audio recordings will be stored on a Duke encrypted laptop and will be available only to authorized study personnel as necessary to review the content of the sessions. All audio recordings will be destroyed at the end of the study.

<u>Confidentiality for Texting Reminders</u>

Many companies and applications on your smartphone commonly use work with text platforms and cloud-based companies to send and receive information. We use Twilio to send you text messages. Text messaging does not provide a completely secure and confidential means of communication, and the messages are unencrypted. Twilio encrypts your information on their servers, but no system is completely safe. If they decide to share these data, it may no longer be covered under the privacy protections. Information that identifies you, such as your phone number, may be sent to and permanently kept by Twilio and their business associates. Information disclosed to these companies or their business partners, it may no longer be covered under the privacy protections. Because text messaging does not provide a completely secure and confidential means of communication, if you wish to keep your communication completely private, please let us know, and we will communicate with you only through regular channels like the telephone and email.

We will not share mobile information or SMS opt-in data with third parties or affiliates for marketing or promotional purposes. Sharing of mobile information is strictly limited to subcontractors providing essential support services, such as customer service, and only as necessary to fulfill those services.

Do you want to receive text messages as part of this study?
If yes, you consent to receive SMS text notifications from the WHEEL Program for WHEEL session and survey reminders and for payment purposes. Message frequency varies. Standard message and data rates may apply. You may change your texting preference (start or stop texting reminders) at any time by emailing the study team.

- Yes
    - Please provide your phone number to receive study-related texts.

      ____
- No

The digital voice and video recordings at Duke will be destroyed after publication of the study's main findings. All hard copies of data and electronic files, except for recordings, will be stored securely at Duke University for up to five years after completion of the study. The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain confidential. If you decide to share your information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Will it cost me anything to be in the study?

There are no additional costs to you for participating in this study. You and your insurance company will not be billed for your participation.

Will I be paid to be in the study?

You will receive up to $75 for completing surveys, $25 per survey. If invited to participate in the interview, you can earn $50 for participating in the interview. You will only be paid for the surveys and interview you complete. In order to issue your payment, Duke University may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

What about research-related injuries?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

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For questions about the study or research-related injury, contact Dr. Rogers at 919-681-2045 during regular business hours and at 919-681-2045 after hours and on weekends and holidays.

What if I want to withdraw from the study?

If you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you withdraw from the research, you will not be able to continue the online program, complete surveys, or participate in the interview. If you do decide to withdraw, we ask that you contact Dr. Rogers in writing and let them know that you are withdrawing from the study. Their address is jennifer.rogers3@duke.edu. You will be asked to return any study materials sent to you, not including the study notebook.

The study doctor may decide to take you off this study if you miss 3 group sessions or are not able to attend all health coach sessions. The study doctor may also decide to take you off this study if she determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time. If this occurs, you will be notified and your study doctor will discuss other options with you.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

The use of your data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://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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Whom should I call if I have questions or problems?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Rogers at 919-681-2045 during regular business hours and at 919-681-2045 after hours and on weekends and holidays.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

STATEMENT OF 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, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Participant	Date	Time
Signature of Person Obtaining Consent	Date	Time