Title: Self-Guided Resilience-Building Energy Management to Enhance Well-being (RENEW) Intervention for People With Systemic Sclerosis (SSc)

NCT Number: NCT07402863

Study ID: HUM00266174 / Amendment ID: Ame00159493

Approval Date: 1/3/2025

Document Finalized: 3/20/2025

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Self-Guided Resilience-Building Energy Management to Enhance Well-being (RENEW) Intervention for People with Systemic Sclerosis: A Feasibility Study

Company or agency sponsoring the study: No sponsor.
Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Susan Murphy, ScD, OTR, Department of Physical Medicine and Rehabilitation

Study Coordinator: Elizabeth Haro, MPH, Department of Physical Medicine and Rehabilitation

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

We are currently conducting a pilot study to evaluate our RENEW app, which has been specifically designed to support individuals living with scleroderma. In this study, participants will be asked to download the RENEW app onto their personal devices. Through the app, they will set and track their weekly healthy goals throughout the 12-week study period. This will enable us to gather important data and valuable feedback, helping us assess the app's effectiveness and usability for people with scleroderma.

Participation in this study is entirely voluntary. Even after you have signed the informed consent document, you may choose to withdraw from the study at any time without any penalty or loss of benefits to which you would otherwise be entitled. In other words, deciding not to complete the study, not to answer specific survey questions, or to stop participating at any point will not affect any benefits or services you currently receive

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. More detailed information will be provided later in this document.

Participants will derive no direct benefits other than the knowledge that they are helping research an important problem. By participating in this study, individuals will be helping to advance our understanding of how to better support people with scleroderma in managing their symptoms through the use of technology. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 24 hours over 12 weeks, reading the online modules and setting and tracking goals using the app. Additionally, there will be three online outcome assessments, scheduled at baseline, 6 weeks, and 12 weeks after the intervention program.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: The primary goal of this study is to examine feasibility and preliminary efficacy of the self-guided RENEW intervention delivered through the mobile app for people with scleroderma.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

You are eligible for this study if you are 18 years or older, have a medical diagnosis of systemic sclerosis (scleroderma), have fatigue symptoms that significantly impact your daily life, have reliable access to an internet connected device like a computer or tablet, and are able to speak and read English

You cannot participate in the study if you are planning to start any new treatments in the 12-week study period for symptoms of fatigue, pain, or depressed/anxious mood such as psychological treatment, structured rehabilitation, or a medication. You cannot participate if you are experiencing other complex medical issues that could impact your study participation. You cannot participate in the study if you are already participating in another similar scleroderma symptom self-management program/study at the same time. You cannot participate in the study if you have previously participated in the RENEW program.

3.2 How many people are expected to take part in this study?

40 subjects are expected to participate in this study at the University of Michigan.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Self-Guided RENEW program

If you choose to participate in this study, you will be involved in several activities. First, you will download the RENEW app onto your personal mobile device. There is no fee for downloading or use. Once the app is installed, you will receive instructions on how to set up your profile and begin using the app for the RENEW program.

The core of the study involves using the RENEW app to set and track your weekly healthy goals related to symptom self-management. The app will guide you through various self-management techniques, providing prompts and reminders to help you stay on track.

Throughout the study, data on your app usage, goal achievement, and survey responses will be collected and analyzed to assess the feasibility and effectiveness of the RENEW intervention. Rest assured that all data collected will be kept confidential and used solely for the purposes of this research. Your feedback on your experience using

the RENEW app at various points during the study will be invaluable to us. Additionally, you will have access to technical support should you encounter any issues with the app.

The study will last for 12 weeks, during which time you will be expected to regularly interact with the app. We will email surveys to you to complete online that ask about your symptoms, mood, and what you thought about self-guided RENEW. We will have you fill out the surveys 3 times: at the start of the study, at the mid-point (about 6 weeks) and at the end of the study (after 12 weeks). We expect it to take about 45-60 minutes to complete the surveys. By participating in this study, you will be contributing valuable information to help us understand how to better support individuals with scleroderma in managing their symptoms through the use of technology. Participation is entirely voluntary, and you may withdraw from the study at any time without any penalty.

A subset of participants will be invited to participate in a 1-hour interview to share their experiences with the Self-Guided RENEW app. Your feedback will help us better understand your experience and improve the app. Participation in the interview is entirely optional, and you are not required to take part.

4.2 How much of my time will be needed to take part in this study?

We estimate that your time commitment is about 24 hours over the 12 weeks.

4.3 When will my participation in the study be over?

You will be done with the study after your fill out the final set of surveys, approximately 12 weeks after you started.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Time burden. We estimate about 24 hours for this across the 12 weeks of the study. You are expected to commit to independently work on lessons from the RENEW program and complete your online surveys in a timely manner (within 1 week of receiving them).

Soreness or breathlessness as you work on moving more. Some of the RENEW lessons involve moving more than usual. You might feel sore or out of breath as you add physical activity to your day. These sensations are temporary, and your can adjust your goals to find a good level for you.

Negative feelings as you work through lessons that address mood and social relationships. RENEW also addresses things like mood and social relationships. If you are struggling with depression or sadness, or feel stress in your interpersonal relationships, reading and talking about these issues could bring on negative feelings. We have several resources that address mental health on the RENEW app. Additionally, you will receive a list of Community Mental Health Resources upon joining the study.

Risks to privacy. Any information like the goals you set and disclose in the app is voluntary. This information is protected on secure University of Michigan servers and databases that only study team members can access.

Additionally, there may be a risk involving loss of confidentiality or privacy. For example, if individuals outside this study were to discover that you were a participant in this research, or if any collected identifiable genetic or health information were disclosed to unauthorized persons, there is a risk of discrimination by employers or insurance providers. The researchers have adopted privacy and confidentiality procedures to help prevent such disclosures. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

Keep in mind, as well, that the committee (IRBMED) that reviews this study does not review risks associated with procedures that are conducted as part of your regular medical care and are not part of the research, including those marked "[Not research]" in section 4.1, above. Risks associated with your regular medical treatment should be discussed with your regular doctor.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them.

Please let us know about any changes in your scleroderma, symptoms, changes in your health, or other problems that you have during this study so that we can prioritize your health and well-being. You should also tell your regular doctors. We may decide to temporarily pause your study participation should you become sick or have any other acute health changes that would make study participation difficult. Additional week(s) will be added to your participation timeline to make-up for those missed so that you can still complete the full 12 weeks of the study. Our contact information is listed Section 10 and on the summary page.

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. You may not participate in similar scleroderma symptom self-management studies throughout the next 12 weeks.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

By being in this study, you might learn new skills or strategies to help you manage your symptoms. We hope the self-guided RENEW program can be included as part of regular medical care if we show that it works through this trial.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

If you choose not to take part in this study, talk to your health care provider if you want medical or psychological treatments to address fatigue and mood symptoms.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why

you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

Tell us if you are thinking about stopping or decide to stop. It is important to tell us if you are thinking about stopping so any risks can be evaluated by the researchers. We will also tell you how to stop safely and discuss what follow-up care and testing could be most helpful for you. If you decide to leave the study before it is finished, please tell one of the researchers listed in Section 10 "Contact Information" (below).

You are free to end your participation partially or completely in the study. An example of partially ending your participation would be to discontinue receiving study intervention, while still allowing continuation of study follow-up procedures.

Please note that any information collected before you withdraw will be kept and used to complete the research.

Please note that even if you withdraw consent for further follow-up or contacts, if the study doctor becomes aware of additional safety information this will be reported to the sponsor to comply with legal or regulatory requirements.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researchers believe that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study.

The study will pay for research-related items or services that are provided only because you are in the study. The procedures described in section 4.1 may include some non-research procedures. Those designated as "[Not research]" will not be paid for by the study. If you are not sure which procedures or services the study will pay for, ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed because of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will receive up to $90 for completing the study tasks. You will receive $30 for completing the baseline survey, week 6 survey and following the week 12 survey. You will get a check in the mail approximately 14 days after you complete each round of surveys.

You will have the option to participate in a follow-up interview to share feedback about your experience in the study. If you choose to participate in this 1-hour interview, you will receive an additional $30 as a thank-you for your time.

International participants only: Due to a fee associated with cashing US checks, you will receive an Amazon e-gift card associated with the appropriate Amazon website for your country. These will be sent via email for $30 per survey you complete, up to $90. You will also have the option to participate in a follow-up interview to share feedback about your experience in the study. If you choose to participate in this 1-hour interview, you will receive an additional Amazon e-gift card of $30 as a thank-you for your time.

8.3 Who could profit or financially benefit from the study results?

No one will profit or financially benefit from the study results.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF PARTICIPANT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Your participation will occur at Michigan Medicine. Your data will be kept confidential, to the extent permitted by applicable laws, in the following manner:

- Your name will not be used in any reports about the study
- You will be identified only by a study code
- Your identifying information will be kept secure

Despite these protections, some study data may contain information that could be used (perhaps in combination with other information) to identify you (e.g., initials, date of birth).

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results and dental records
- Any records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner and for quality improvement purposes.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular Michigan Medicine medical record.
- If you receive any payments for taking part in this study, the University of Michigan finance department will need your name and address for tax reporting purposes. In a calendar year if: 1) your payments total greater than $400 for this study or 2) if you receive payments of greater than $400 for being in more than one study, the University of Michigan finance department will also require your Social Security Number for tax reporting purposes. If you do not wish to provide your Social Security Number, you may continue to participate in research studies, but you will not be able to receive payment for the remainder of the calendar year.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information

- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

If your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission does not expire unless you cancel it. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Susan Murphy
Mailing Address: 24 Frank Lloyd Wright Drive, PO Box 344, Ann Arbor, MI 48106
Telephone: 734-936-2123

Study Coordinator: Elizabeth Haro
Mailing Address: 24 Frank Lloyd Wright Drive, Lobby M, Suite 3100, Ann Arbor, MI 48105
Telephone: 734-936-2123

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

You will receive a copy of the signed and dated informed consent document.

Your signature in the next section means that you have received a copy of the following document(s):

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. STORAGE, USE, AND SHARING OF SPECIMENS AND INFORMATION COLLECTED OR GENERATED IN THE STUDY DESCRIBED ABOVE

12.1 What is meant by the storage, future research use, and sharing of study participants' medical information and leftover samples (sometimes referred to as biospecimens) taken from me?

Individual researchers, the University of Michigan, and companies that design and sponsor studies often want to keep subjects' medical information and leftover samples such as blood, tissue, saliva, and cells to use in future research. These future research uses take different basic forms, which are described below. The medical information and leftover samples may also be shared with other researchers so that they can use it in their studies.

The purpose of storing, using, and sharing participants' medical information and leftover samples is to promote more research that might lead to useful medical discoveries.

In some cases, researchers need your consent to store, use, and share your medical information and leftover samples; in other cases, they can store, use and/or share it without your consent. Whether or not researchers need your consent depends on if the stored information and samples would still be identifiable as yours or whether the researchers would first remove all information connecting them back to you.

12.2 Types of storage, future research use, and sharing in this study

Investigator-initiated research

For purposes of this research study, your collected private information and any biospecimens will be shared with the study sponsor (U-M), its collaborators, and associated research partners.

With appropriate institutional and regulatory permissions, your collected private information and identifiable biospecimens could be used for future research with other researchers and companies, including those in other countries, with or without your consent.

In addition, after identifiers are removed from your private information and any biospecimens, the information and biospecimens could be used for future research studies by U-M and shared with other researchers or companies, including those in other countries, without your additional informed consent.

13. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the researchers keep my specimens for future research (signature required below).

_____ No, I do not agree to let the researchers keep my specimens for future research (no signature).

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

(OPTIONAL) APPENDIX:

INFORMED CONSENT TO A SUB-STUDY