Study: Taking Charge of Systemic Sclerosis

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HRPO Template

1) Protocol Title (Version # and/or Version Date)

Taking charge of systemic sclerosis: Improving patient outcomes through selfmanagement (Version date 8/20/2015)

2) IRB Review History

NA

3) Objectives

The Specific Aims for the current proposal are:

1. To engage Patient Partners and Stakeholders to assess whether the current interactive Internet-based self-management program (Taking Charge Of Systemic Sclerosis) has the information people with systemic scleroderma perceive they need to effectively manage their disease.

2. In a RCT, to assess whether the Internet-based self-management program (revised after Patient Partner, Stakeholder, and focus group input) is superior to the control condition in improving overall self-efficacy (primary outcome measure), and self-management knowledge and skills and other relevant patient-reported outcome measures (physical function, anxiety, depression, fatigue, sleep disturbance, pain interference, satisfaction with social roles, pain, appearance, health-related quality of life, quality adjusted life years.)

4) Background

Because scleroderma is a rare disease (designated as an orphan disease by the Food and Drug Administration), patients living outside major metropolitan areas may not have access to health care providers with a specialized knowledge of scleroderma. Thus, scleroderma patients feel isolated from sources of support and education programs. The only education programs specifically focused on scleroderma were developed in Sweden, the United Kingdom, and the Netherlands. These 3 programs used traditional group sessions that require patients come to central locations, which can be difficult for those with mobility issues or fatigue. Furthermore, there may not be enough scleroderma patients in a geographic area to support an education program. Creators of the Arthritis Self-Management Program and Chronic Disease Self-Management Program have developed Internet versions of their successful programs. However, these existing programs do not address the specific needs of scleroderma patients, such as body image changes, skin and ulcer management, hand contractures, Raynaud’s phenomenon, and lung and gastrointestinal involvement.

To address the lack of educational programs for scleroderma patients, Drs. Poole and Mendelson, with input from patients with systemic scleroderma and scleroderma experts (including coprincipal
investigator [PI, Dr. Khanna), developed a print format self-management program with an exercise DVD. Pilot testing of the print version by people with scleroderma showed improved self-efficacy for managing pain and verified the content and need for such a program. Participants also voted on a name for the program, “Taking Charge Of Systemic Sclerosis (TOSS).” We subsequently converted the program to an interactive Internet version. Participants who took part in the pilot online version proceeded through the modules at their own pace. They were able to download resources, exercise programs, learning activities, and worksheets. Furthermore, an audio “voice-over” of the text for each module was done to accommodate low literacy and participants who experienced fatigue while reading the computer screen or had problems manipulating the keyboard.

We recently published the findings from our successful pilot trial of the Internet version, which showed increased self-management knowledge and skills and reduced symptoms of fatigue and depression. Furthermore, qualitative data from the Discussion Boards and participant evaluation surveys suggest that participants felt the content was important and appropriate, and reaffirmed or provided new information; participants also felt that the exercise video was very useful. Our qualitative and quantitative data support a critical need for an adequately powered comparative effectiveness study to determine whether the Internet-based self-management program results in better patient-reported outcomes compared with an authoritative educational book, The Scleroderma Book: A Guide for Patients and Families, by Dr. Maureen Mayes.

This proposal is for collaborative project with partners (people with scleroderma and stakeholders) designed to refine an internet program for patients with scleroderma and to compare the internet program to an authoritative educational book. In HUM00096821, Patient Partners, Stakeholders, and scleroderma patients participated in focus groups and collaborated with the investigators to evaluate and revise TOSS, the existing self-management program. Individuals with systemic sclerosis known to the investigators for their participation or leadership in support groups were recruited in Michigan, South Carolina and Southern California. Several focus groups with a total of 30 participants with SSc were conducted: 2 telephone groups and 4 face-to-face groups. The participants were 63% female, 70% Caucasian, 67% had diffuse systemic sclerosis, the mean age was 48.8 years, mean disease duration was 11.4 years, and the mean education level was 15.8 years. Each focus group lasted 2.0-2.5 hours in duration. Dominant themes for additions to the current website: format changes and additional pictures, affect and positive affirmation; disease and symptom management; self-advocacy; information for use by caregivers, families, coworkers and strangers; tracking systems for medical records, tests and symptoms; and information about local support groups.

We will now proceed with comparative effectiveness, using a 16-week RCT, we will recruit 250 patients who will be randomized to either TOSS or authoritative book for patients, The Scleroderma Book: A Guide for Patients and Families.

5) Inclusion and Exclusion Criteria

Inclusion criteria for:
All participants will be residents of the United States, diagnosed with systemic scleroderma, and 18 years of age; will possess basic computer literacy and have access to a computer with Internet and email capabilities; and will have the ability to communicate in English and a willingness to complete the study protocol. If participants meet the inclusion criteria and express an interest in participating, residence will be verified by asking participants for their mailing addresses in order to send the consent forms.

Exclusion criteria:
Not having access to or experience using a computer with Internet and email capabilities, unwilling to complete the study protocol, and unable to communicate in English.

6) **Number of Subjects (Recruitment Target)**

The maximum number of participants is 250 participants.
There are 3 sites (UNM, University Michigan, Medical University of South Carolina) but no predetermined number of participants accrued at each site.
Dr. Poole at UNM will recruit from the Scleroderma Foundation and their chapters, and Scleroderma Research Foundation.
Dr. Khanna at UM will recruit from the UM Scleroderma Database
Dr. Silver at MUSC will recruit from the MUSC Database.

There is no set number of subjects who need to be screened in order to meet recruitment goals.

**Sample size determination:**
Our sample size calculation is based on analysis of pre–post changes in the Chronic Disease Self-Efficacy Scale in our preliminary Internet study. Based on preliminary data, we expect that the effect size (ES; mean pre–post change/SD) in the intervention group will be approximately 0.50 (7.2/14.3; medium effect size as suggested by Cohen), and we anticipate a negligible effect size in the control group (ES = 0.10). Assuming an alpha of .05 (2-sided test), we will need 100 patients in each group to have 80% power for detecting this difference between the intervention and control groups. We assume a conservative attrition rate of 25% during the study, so we will need to enroll a sample size of 125 patients in each group.

7) **Recruitment Methods**

Individuals with systemic scleroderma will be recruited from the Scleroderma Foundation website and through announcements sent to local chapters of the Scleroderma Foundation, the Scleroderma Research Foundation, and clinics at the University of Michigan and Medical University of South Carolina (see below). Dr. Poole has successfully recruited patients from the Scleroderma Foundation and chapters for studies on self-management, parenting, and work and functional disability. These recruitment efforts have yielded diverse samples of individuals from all geographic areas across the United States.
Drs. Khanna and Schiopu will recruit from his patients at the University of Michigan Scleroderma Program and will secure IRB approval from the UM. The Scleroderma Program at the Medical University of South Carolina is led by Dr. Rick Silver, who also directs the Multidisciplinary Clinical Research Center (MCRC) for the Study of Rheumatic Diseases in African Americans, funded by NIAMS. Dr. Silver will recruit from his patients and secure IRB approval from the MUSC IRB.

Dr. Poole at UNM will recruit from the Scleroderma Foundation and their chapters, and Scleroderma Research Foundation using flyers and advertisements placed on their websites. Recruitment materials (scripts to recruit focus group members and advertisements for the RCT) have been attached.

8) Study Timelines

The duration of participation by individuals will be over a period of 10 months (16 weeks and 6 month follow-up).

All study participants should be enrolled by August 31, 2016

PCORI grant is 3 years in duration so it is estimated that we will compete the study by August 31, 2017.

Focus groups were completed by April 26th, 2015
RCT and post intervention questionnaires completed by January 31, 2017
6 month follow up completed by August 31, 2017 All data analyzed by July 31, 2017.

9) Study Endpoints

N/A

10) Research Setting

The interventions (logging on to the website and viewing the modules OR reading the book) will be done in participants’ homes or a site convenient to them since they complete these at their convenience.

11) Study Methods

This proposal is for collaborative project with partners (people with scleroderma and stakeholders) designed to refine an Internet-based self-management program for patients with scleroderma and to compare the Internet program to an authoritative educational book. In HUM00096821, Patient Partners, Stakeholders, and scleroderma patients participated in focus groups and collaborated with the investigators to evaluate and revise TOSS, the existing selfmanagement program. During this study, we will conduct a comparative effectiveness phase, using a 16-week RCT, we will recruit 250 patients who will be randomized to either
TOSS or authoritative book for patients, The Scleroderma Book: A Guide for Patients and Families

After signing a voluntary consent form electronically through Qualtrics, participants will be invited to complete online pre-intervention questionnaires. The participants will be randomized to two groups by Dr. Veronica Berrocal, PhD, a biostatistician, at UM using a computer block randomization and a 1:1 ratio. Patients will be assigned to either the Internet program or the education book group. Although the assignment to either group is random, to make sure that the proportion of patients with depressive symptoms are approximately the same in both groups, after every 50 patients recruited, the assignment of patients to each group up to that point will be cross-tabulated with respect to depressive symptoms on the PHQ-8. Depressed mood was identified by patient partners as a key determinant for coping and helplessness and a covariate that can influence the primary outcome measure. If the intervention and control groups are not similar with respect to this variable or other variables related to depressed mood, assignments to either group for the next 50 patients will be administered randomly while trying to make the distributions of patients characteristics assigned to the two groups more similar. For example, if by chance patients with more severe symptoms have been allocated to the treatment group, randomization of the next 50 patients will be carried out so that patients with less severe symptoms are more likely to be assigned to the treatment group. The same verification process would be performed for the next set of 50 patients, and so forth.

Patients randomized to the active treatment intervention will be assigned to the Internet program. The site will be accessed via secured website. The modules will be presented 1-2 per week. The Patient Partners and Drs. Newbill and Poole will post weekly questions regarding the modules on the Discussion Board and Drs. Newbill and Poole will moderate the online discussion as necessary. Participants will be asked to log on to the Discussion Board at least once a week.

Participants in the control group will receive a copy of The Scleroderma Book: A Guide for Patients and Families, by Dr. Maureen Mayes. We chose this book to be the comparator because it is the authoritative, educational book most requested and used by patients with diagnosis of scleroderma. To date, it is the only credible resource written for patients and includes sections on early diagnosis, symptoms, coping with the disease, and resources for patients.

Outcome Measures

Demographics. Demographic information will be collected to describe the sample, including age, gender, type of scleroderma (diffuse, limited, overlap disease), length of time since disease onset and symptoms, self-rated health, education level, marital status, and ethnicity.

Patient Health Questionnaire-8 (PHQ-8), an 8 item questionnaire, will be used to measure depressive symptoms.
Health Log. While enrolled in the study, participants will keep a log of health-related events, such as visits to a physician, days sick, days confined to home, and visits to the emergency room. Pop-ups on the website and email reminders to controls will remind participants to keep track of health-related events.

*PROMIS Self-Efficacy Scale for Managing Symptoms* is an 8 item questionnaire measures confidence in managing symptoms.

*PROMIS Self-Efficacy Scale for Managing Daily Activities* is an 8 item self-report scale that measures perceived self-efficacy or confidence to perform specific tasks or behaviors of daily living.

*PROMIS Self-efficacy Scale for Managing Medications and Treatments* is an 8 item self-report that measures confidence in understanding and taking medications and treatment.

*PROMIS Self-efficacy Scale for Managing Emotions* is an 8 item scale that measures confidence in handling emotions, stress and feelings and anxiety.

*PROMIS Self-efficacy Scale for Managing Social Interactions* is an 8 item scale that measures confidence in maintaining social activities and getting support from others.

The *Patient Activation Measure*. This self-report questionnaire consists of 13 items and assesses confidence in self-management of one’s chronic condition.

*Brief Satisfaction with Appearance Scale (SWAP)* is a 6 item scale measuring body image concerns and social discomfort with body parts.

*PROMIS-29 Profile v2.0 Measure*. The PROMIS-29 Profile v2.0 measure contains 29 items, which includes 4 items each from physical function, anxiety, depression, fatigue, sleep disturbance, pain interference, and satisfaction with social roles domains, and a single item on pain intensity. With the exception of physical function, which does not include a time frame, all item banks reference the past 7 days. PROMIS 29 provides domain scores, similar to SF36.

*European Quality of Life-5 Dimensions (EQ-5D) and Quality Adjusted Life Years (QALYs)*. The EQ-5D is patient preference measure commonly used in comparative effectiveness research. It is a generic health-related quality of life instrument that incorporates patient-reported outcomes along the domains of mobility, self-care, activity, pain, and anxiety. These domains are significantly impacted by scleroderma. Using a conversion algorithm, patient responses are converted into a health utility measure, ranging from 0.0 (death) to 1.0 (full or optimal health). Through measuring health utility using the EQ-5D at baseline and at the end of the study, QALYs gained over the study period will be determined and compared between the study groups.

**Study Procedures**

Participants who are interested and meet the inclusion criteria will be invited to participate either in person, via telephone script or email script. Subjects who are invited in person will be provided a handout with instructions to review an electronic consent form through Qualtrics. Once the signed consent is reviewed, participants will be invited to complete the baseline
questionnaires using Qualtrics, a password protected website maintained at the University of Michigan server which only the research team will have access to. Participants who complete the questionnaires and consent on Qualtrics will be randomized to either an intervention or control group using a 1:1 ratio and computer-generated block randomization, and will be stratified based on scores on the PHQ-8 to ensure one group is not comprised of participants who have more severe depressive symptoms than the other.

The **intervention group** will be sent the link to the self-management website. Participants will be expected to complete the program in 16 weeks. Because we will be recruiting from clinics and the website on regular basis, we will start the intervention participants in groups of 10-12 to help decrease attrition. In keeping with the spirit of self-paced interventions, once participants are entered into the intervention, they will be able to progress at their own pace. We will be able to track whether people log in and the time spent on the Internet program. We will contact participants personally if we notice inactivity. Drs. Newbill, Poole, and the Patient Partners will post questions or discussion points weekly on a Discussion Board to keep interest in the program.

Participants randomized to the **control group** will be sent Dr. Mayes’ textbook. The control group will have 16 weeks to read the book; we will contact participants, either through email or by phone, at 4, 8, 12, and 16 weeks to check on the progress with the book.

At the end of the intervention period, participants in both groups will complete the postintervention questionnaires using Qualtrics. In addition, immediately, post-intervention, the participants in the intervention group will also be directed to complete a program questionnaire in which they are asked to evaluate the content and presentation of the modules and provide other feedback to the investigators. To assess whether improvements in self-efficacy and knowledge during the 4-month intervention period are sustained, we will administer questionnaires to the patients in both groups at 6 months post-intervention. In addition, in keeping with the spirit of patient centeredness, after the 6-month follow-up, the control group will be provided access to TOSS, the Internet self-management program. A variety of strategies will be used to maintain participant engagement in both groups during the intervention, such as phone calls or email contact at 4, 8 and 12 weeks and a small incentive at midpoint.

Direct identifiers (name, address, email address, phone numbers) will be collected and maintained to send gift cards, contact participants during intervention, and to contact/remind participants to complete questionnaires pre-intervention, post and 6 month follow-up. The links will be kept on a password protected computer in a file separate from the data file.

No drugs or devices are used in this research.

Copies of all data collection forms, including questionnaires are attached as appendices.

Participants in both the intervention and control groups will be sent gift cards at different points in time for up to a total of $150.

- Upon completing the baseline questionnaires, participants will receive a gift card for $25.
• At the midpoint period of the intervention, participants will receive a gift card for $25 for logging in to the modules and discussion board OR reading the book?
• At the 16 week period, upon participating in the intervention or control group for the 16 weeks and completing the questionnaires a second time, participants will receive a gift card for $50.
• At the 6 month follow-up, upon completing the questionnaires a final time, participants will receive a gift card for $50.

12) Data and Specimen Banking

NA. Data will not be stored to use for future analysis.

13) Data Management

The following PHI will be collected: Age, gender, education level, type of scleroderma, ethnicity, length of time since disease onset and symptoms, marital status, and employment status.

There will be a link between identifiers and data for the purpose of notifying participants to complete the post-intervention questionnaires and the 6-month follow up. The link will be stored on a password protected computer at the University of Michigan in a locked office of the study team. The link will be kept for the length of the grant, until August 31, 2017 and destroyed according to UNM destruction policy.

The PIs and co-Is including the statistician, Dr. Veronica Berrocal, PhD at UM will have access to the data.

Participants in both the intervention and control group will be sent a link to complete the questionnaires using Qualtrics (pre, post and 6 months post intervention). This password protected database will be stored on password protected computer at UM in the locked office of the study team. Responses to the Discussion board questions are stored as part of the Selfmanagement internet website which can only be assessed by the participants in the Intervention group and the investigators. There are no identifiers associated with the responses on the Discussion board.

Data Analysis:

Qualitative Analysis of Discussion Board Posts:
Discussion Board posts will be qualitatively analyzed using content analysis to identify the key content and establish baseline codes that can serve as a preliminary outline or framework of the key points in the data. This process will be followed by immersion and crystallization, which is an iterative, contemplative, and reflexive approach to data analysis. The researcher (Dr.Newbill) will immerse herself in the data “leading to the emergence of insights and
interpretations. She has extensive experience in conducting this type of analysis. The first read of the data provides a gestalt of the experience from the participant’s perspective. Successive readings and reflection on the data assist in the process of crystallization of insight and meaning. At the conclusion of the crystallization process, the investigator will have generated a series of thematic statements and the essential components of the stories (subthemes) that account for the experiences discussed by the participants.

**Analysis of Data From RCT:**

Data will be entered into an Excel database and then transferred to SAS or any other appropriate statistical software for analysis. The primary outcome measures (PROMIS Self-Efficacy Scale for Managing Symptoms, Patient Activation Measure) and other scales (PHQ8, PROMIS Self-Efficacy Scale for Managing Daily Activities, PROMIS Self-efficacy Scale for Managing Medications and Treatments, PROMIS Self-efficacy Scale for Managing Emotions, PROMIS Self-efficacy Scale for Managing Social Interactions, Brief Satisfaction with Appearance Scale (SWAP), PROMIS-29, and EQ-5D, QALY) will be scored, and pre–post differences will be calculated. Descriptive statistics will be computed for demographic characteristics and outcome measures, and the distributions of pre–post changes will be evaluated for normality. The primary analysis will assess the difference in the changed scores between the intervention and control groups. Significant differences in changed scores between the 2 groups will be determined using paired t tests if the distributions are approximately normal or can be transformed to be approximately normal. If the distributions are not normal, then the Wilcoxon signed rank test will be used to test whether the differences are significant or not. A multivariate generalized linear model will be fit to the changed scores data to determine whether covariates such as education and time since diagnosis had a significant effect on the pre–post difference in the 2 groups besides the treatment (that is, access to the self-management Internet program).

Additionally, to account for variability among patients due to the site of recruitment, a random effect for site will be included in the generalized linear model above. The site-specific random effect will allows us to control for the fact that some sites might recruit more patients than others.

Eventual missing data will be handled by first determining through exploratory analysis whether it is missing at random or not. For this purpose, we will calculate summary statistics of the primary outcome measures at baseline for those patients who have completed the study (completers) and for those who have not (noncompleters). If there are significant differences between the groups, then data is not missing at random. If the data are missing at random, then the Wilcoxon signed rank test will be used to test whether the differences are significant or not. A multivariate generalized linear model will be fit to the changed scores data to determine whether covariates such as education and time since diagnosis had a significant effect on the pre–post difference in the 2 groups besides the treatment (that is, access to the self-management Internet program).
significant differences in the changed primary outcome measures between the control and intervention group using only the completers and using the entire set of patients with imputed missing values. This will allow us to evaluate the sensitivity of our results to the data imputation mechanism. If the exploratory analysis indicates that the data are not missing at random, we will expand our statistical model to include a model for the missing data mechanism. In a nutshell, a binary variable indicating whether an observation is missing or not will be created, and the complete data model will include the multivariate generalized linear model described above and a logistic regression model linking the probability that an observation is missing in some variables we believe are important in explaining the likelihood of a missing observation (for example, demographic characteristics, severity of the disease, etc.).

Analysis of EQ-5D and QALYs. EQ-5D measures will be collected at baseline and at the end of the study. EQ-5D responses will be compared between study groups within each domain (mobility, self-care, activity, pain, and anxiety). EQ-5D results will also be converted into health utility values using the US conversion algorithms. The change in health utility scores will be multiplied by the portion of a year elapsed during the study (16 weeks/52 weeks = 0.308) to determine QALYs gained during the study. Mean values of QALYs gained will be compared between study groups to determine the impact of the intervention on QALYs.

Program Evaluation

Program evaluation will focus on the participants’ perceptions of the value and usefulness of the self-education program, their suggestions for improvement, and their evaluation of the benefits of the support provided to complete the program. Analysis of program evaluation data will include computation of descriptive statistics for the variables on the program evaluation questionnaire. The time spent on the website intervention activities, including the Discussion Board, which was calculated during the logins, will also be tallied.

This is NOT a VA study.

14) Provisions to Monitor the Data to Ensure the Safety of Subjects

There is no data safety monitoring board because there is no pharmaceutical intervention and the risks are minimal. The PI’s contact information will be provided on the consent forms should participants have any questions or concerns. Dr. Poole will check in with Dr. Newbill, who will be monitoring the Discussion Board. Because participants can log into the Discussion Board 24/7, it is not possible to monitor the comments in real time. However, should Dr. Newbill or Dr. Poole see any disparaging or desperate comments made by any participants, the participants will be contacted by telephone or email. Furthermore, participants who have not logged in for more than 2 consecutive weeks will be contacted by email or telephone.
15) **Withdrawal of Subjects**
If participants withdraw from the research during the intervention phase, we will remove access to the website and will not send them the post or follow-up questionnaires. Information from the pre-invention questionnaires will be considered for data analysis.

The investigators have the right to end participation in this study if they determine that participants no longer qualify to take part, do not follow study procedures or if it is in their best interest or the studies best interest to stop participation. The investigators may end participation if participants in the control group are not responding to phone calls and it does not appear that they are reading the book. Investigator may end participation if participants in the intervention group are not logging on to the website and viewing the modules or logging on to the discussion board (intervention group).

16) **Risks to Subjects**
There is a small risk of loss of confidentiality, to minimize this risk we have adopted strict privacy and confidentiality procedures. There may be risks of stress, emotional distress, and inconvenience in having to log into the website, learning more about systemic sclerosis and managing symptoms and participating in discussion boards. People may experience some emotional upset and loss of privacy as a result of talking about the illness in the Discussion Boards but this is probably no greater than the risk of daily living with the disease. Participants do not have to share any information that they do not want to or answer any questions that they do not want to. Participants can log in and read others comments without having to share any of their information.

17) **Potential Benefits to Subjects**
There may or may not be direct benefit from being in this study. However, participation by participants in both phases may help participants find out ways people with scleroderma manage the disease that may or may not be useful. Participation may help develop and refine information included in the website on self-management for systemic sclerosis.

18) **Vulnerable Populations**
No vulnerable populations are included.

19) **Multi-Site Research**
There are 3 sites participating in this study, University of Michigan and the Medical University of South Carolina and the University of New Mexico. They will be recruiting participants only from their own patient databases and will obtain their own IRB approval and approval for the electronic consent used by Qualtrics. University of Michigan will be the data coordinating center. Each site will obtain approval from their respective IRB, using the electronic consent, and HIPAA documentation. Any modifications will be approved by all 3 IRBs before modifications are implemented. Any non-compliance with the protocol or applicable
requirements will be reported in accordance with local policy and communicated with the other sites and IRBs.

Copies of reporting of adverse events will be sent to all sites.

All 3 sites will work together to determine and report interim results.

All 3 sites will work together to develop the appropriate documents needed to close a study

20) **Community-Based Participatory Research/Field Research**  N/A

21) **Sharing of Results with Subjects/Incidental Findings**

Some of our participants will hear the results of the research at a presentation at the Scleroderma Foundation annual conference or the Scleroderma Research Foundation. We will also submit a summary of our findings to be put on the SF and SRF websites and /or newsletters.

22) **Resources Available**

Janet Poole, PhD, OTR/L (PI), is an occupational therapist and tenured professor of medicine. Her research has examined the impact of scleroderma on daily life, including work, parenting, leisure activities, and self-management. Sharon Newbill, PhD is an experienced qualitative researcher. Dr. Raisch has a specialty in pharmacy and pharmacoconomics and will help analyze the health-adjusted quality of life years and health utility.

Dinesh Khanna, MD, MS (co-PI), is a tenured associate professor of medicine, Director of the University of Michigan Scleroderma Program, and an expert in patient-reported outcome measures, including having served as the PI on an NIH PROMIS project. He has extensively published on patient-reported outcomes in different rheumatic diseases. The PIs have worked together as a team to develop the Internet self-management program. Dr. Berrocal is an Assistant Professor of Statistics at the University of Michigan School of Public Health and has extensive knowledge regarding variables used in scleroderma research.

Richard Silver, MD (co-I), Director of the Scleroderma Clinic at the Medical University of South Carolina and the MCRC for the Study of Rheumatic Diseases in African Americans funded by NIAMS, will help recruit African American patients.

Other members of the research team consist of, Patient Partners, and Stakeholders from the Scleroderma Foundation and Scleroderma Research Foundation. The Patient Partners are people with systemic scleroderma who are known to the PIs and have collaborated with the PIs in the delivery of education programs at support groups or annual local or national patient conferences. The stakeholders are the two national organizations in the United States that provide information/educational materials specifically to people with scleroderma. Per PCORI, teleconference calls are scheduled every 1-2 months. When patient partners have completed the CITI training and are added and approved as study team members, they will be trained by Dr. Newbill to co-conduct the focus groups with her.
Feasibility of your recruitment plan/ access to potential recruits: Systemic scleroderma affects women (4:8:1) and the mean age of onset is 50 years. Therefore, our study will recruit more women. Both University of Michigan and Medical University of South Carolina scleroderma programs see patients with different ethnicities and races at their centers. The University of Michigan Scleroderma Program has a patient population of more than 1500 scleroderma patients. The Program averages 8-10 new patients per week and has a referral system that serves the Midwest, from Chicago through Cleveland. The Program continues to see referrals from the northeastern and southern United States as well. The Scleroderma Program at the Medical University of South Carolina complements the University of Michigan, as it has a large minority patient population. It averages 1-2 new patients per week and has a referral system that serves the southeastern part of the United States.

Dr. Poole will recruit from the Scleroderma Foundation and Scleroderma Research Foundation to allow us to recruit across the United States to reach those in rural and urban areas. CTSC resources are NOT being accessed.

23) Prior Approvals/Attachments Requiring Signatures

Departmental Review Form attached.

There are no radiation exposures or biological specimens or drugs involved in this study.

24) Confidentiality

Direct identifiers (name, address, email address, phone numbers) will be collected and maintained to send gift cards, contact participants during intervention, and to contact/remind participants to complete questionnaires pre-intervention, post and 6 month follow-up. Identifiable data will be stored on a password protected computer in the PIs’ offices until the end of the study August 31, 2017.

There is no tissue collected.

The PIs and co-Is including the statistician, Veronica Berrocol, PhD at UM will have access to the data.

25) Provisions to Protect the Privacy of Subjects

Individuals with systemic scleroderma will be recruited from the databases from the University of Michigan, the Medical University of South Carolina, and the Scleroderma Foundation and Scleroderma Research Foundation websites and through announcements sent to local chapters of the Scleroderma Foundation (the investigators have used these sources successfully in the past). All potential participants will be instructed to contact the PIs or coordinators by phone or email if they are interested in participating in the study. The PIs or coordinators will screen participants to ensure that they meet the inclusion criteria. For participants meeting the inclusion criteria, the PIs or coordinators will explain the purpose of the study and the study procedures. Participants who meet the inclusion criteria and indicate a
desire to participate in the study will be sent the link to read and complete the consent form. The PIs and study coordinators will be available by email or telephone to answer any questions. Participants will be directed to complete the pre-intervention questionnaires once they review and agree to the electronic consent form or once they have signed a consent form in person. Once the pre-intervention questionnaires are completed, the coordinator will refer to a random allocation sequence to determine the participant’s assignment to group. The random allocation sequence will be generated by the statistician, Dr. Berrocol. The statistician and investigators will have access to the database with information about the participants. However, the database to be used for statistical analyses will be de-identified. PHI is being collected and HIPAA is part of the consent forms.

26) **Compensation for Research-Related Injury**

No research related injuries are expected to occur.

27) **Economic Burden to Subjects**

There are no costs to participants for being in this study.

28) **Consent Process (including waiver request for HIPAA, waiver of HIPAA for recruitment only, Waiver of Informed Consent, and Alteration of Informed Consent)**

**Consent**

Individuals with systemic scleroderma will be recruited from the University of Michigan, the Medical University of South Carolina, and the Scleroderma Foundation and Scleroderma Research Foundation websites and through announcements sent to local chapters of the Scleroderma Foundation (the investigators have used these sources successfully in the past). All potential participants will be instructed to contact the PIs or coordinators by phone or email if they are interested in participating in the study. The PIs or coordinators will screen participants to ensure that they meet the inclusion criteria. For participants meeting the inclusion criteria, the PIs or coordinators will explain the purpose of the study and the study protocol. Participants who meet the inclusion criteria and indicate a desire to participate in the study will be sent an email with a link to review and complete the electronic consent form through Qualtrics. Thus, the consenting process can be done either electronically or in person. The PIs and study coordinators will be available to answer any questions by telephone. Once the consent form is completed, participants will be directed to complete the pre-intervention questionnaires using Qualtrics. The consent form and questionnaires must be completed to participate. Once consent is obtained and the pre-intervention questionnaires complete on line through Qualtrics, participants will be randomly assigned to a treatment condition.
HIPAA Authorization

PHI collected includes age, gender, education level, type of scleroderma, ethnicity, length of time since disease onset, marital status, and employment status. This information is necessary to describe our population and to ensure our participants in the intervention and control groups are similar and for generalization of the findings.

There is a separate HIPAA authorization form.

Only English speaking subjects are eligible. No cognitively impaired adults are eligible.

29) Drugs or Devices

N/A. There are no drugs or devices involved with this study