#### Article type : Original Article

A Randomized Controlled Trial to Evaluate an Internet-Based Self-Management Program in Systemic Sclerosis

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the <u>Version of Record</u>. Please cite this article as <u>doi:</u> 10.1002/acr.23595

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**Objectives**: A pilot study showed that an internet-based self-management program improves self-efficacy in systemic sclerosis (SSc). The objective of the present study was to compare the

internet-based self-management program to an educational book developed for people with SSc in measures of self-efficacy and other patient-reported outcomes.

Methods: A 16-week randomized, controlled trial.

**Results**: Of the 267 participants who completed baseline questionnaires and were randomized to the intervention (internet) or control (book) condition, 123 (93%) in the internet and 124 (94%) in the control completed the 16-week RCT. The mean (SD) age of all participants was 53.7 (11.7) years, 91% were female, and 79.4% had some college or a higher degree. The mean (SD) disease duration after diagnosis of SSc was 8.97 (8.50) years. There were no statistical differences between the 2 groups for the primary outcome measure (PROMIS Self Efficacy Managing Symptoms: mean change of 0.35 in the internet group vs. 0.94 in control group, p=0.47) and secondary outcome measures, except the EQ5D visual analog scale (p=0.05). Internet group participants agreed that the self-management modules were of importance to them, the information was presented clearly, and the website was easy to use and at an appropriate reading level.

**Conclusion:** Our RCT showed that the internet-based self-management website was not statistically superior to an educational patient-focused book in improving self-efficacy and other measures. The participants were enthusiastic for the content and presentation of the self-management website.

#### Significance of Innovation

- 1. Systemic sclerosis (SSc) is a rare disease with many patients who do not have access to education programs.
- We performed a randomized controlled trial comparing an internet-based selfmanagement program to an educational book in measures of self-efficacy and other patient-reported outcomes.
- 3. Self-management website was not superior to an educational patient-focused book in improving self-efficacy and other measures.

4. The participants were enthusiastic for the content and presentation of the selfmanagement website and endorsed it for dissemination.

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#### Introduction

Systemic sclerosis (SSc) is a rare autoimmune disease that universally affects the skin and is associated with aberrant vasculopathy and fibrosis of internal organs(1, 2). Currently, there is no cure for SSc. In addition to having the highest mortality rate among the rheumatic diseases, SSc manifests with disfigurement, hand contractures, fatigue, poor sleep disorders, low self-esteem, pain, and severe Raynaud's phenomenon—all associated with significant functional and work disability, and a decrement in quality of life. In addition, loss of productivity in the United States is estimated to be \$10,764 per year(3).

Because SSc is a rare disease, many people with SSc do not have support or access to education programs or support groups. To address the lack of educational programs, a self-management program consisting of a workbook and DVD was developed and then tested in a small sample of participants with SSc(4). Improvements in pain, depression, and fatigue, as well as positive feedback from the participants, led to the conversion of all the modules in the booklet and the DVD to an internet format. In a pilot study of the internet version of the self – management program, participants logged on to a website and proceeded through the modules and learning activities at their own pace over 10 weeks(5). Participants were encouraged to log on to the Discussion Board, an interactive component of the website, and respond to discussion questions posted for each module. The pilot study showed statistically significant and positive changes for self-efficacy, ability to manage care, health efficacy, fatigue, and depression(5).

Since the initial development of the self-management program, new therapies and recommendations for laboratory and diagnostic tests and pharmacological treatments have emerged(1). Thus, the self-management program was revised and updated with input from patient partners and stakeholders (Scleroderma Foundation and Scleroderma Research Foundation)(6). This article reports on a randomized controlled trial (RCT) conducted to

evaluate the efficacy of the internet-based self-management program vs. the patient book developed for people with SSc in improving self-efficacy and other patient-reported outcome measures. We hypothesized that the internet-based self-management program was superior to the patient book in primary (self-efficacy) and secondary patient-reported outcome measures.



#### Methods

Participants

Individuals with SSc were recruited from the University of Michigan and the Medical University of South Carolina (identified by scleroderma clinics), and via websites and social media sources of the Scleroderma Foundation and Scleroderma Research Foundation (selfidentified SSc). Inclusion criteria were: residents of the United States, diagnosis of SSc, ≥18 years of age, basic computer literacy, access to a computer with internet and email capabilities, communication skills in English, and a willingness to complete the study protocol. This study was conducted in accordance with the Helsinki Declaration and all participants provided informed consent. The study was approved by institutional review boards of the University of New Mexico, University of Michigan, the Medical University of South Carolina, and is registered with clinical trials.gov (#NCT02494401).

#### **Outcome Measures**

#### Demographics

Demographic information, including age, gender, type of scleroderma (diffuse, limited/sine, overlap disease) as reported by the participant, length of time since disease onset, self-rated health, education level, marital status, and ethnicity, was collected.

#### Patient-Reported Measures

Self-efficacy is the belief that one can carry out a behavior necessary to reach a desired goal, even when a situation contains unpredictable and stressful elements(7). Self-efficacy is a major determinant of behavior and behavioral change, and acts as a key mediator of attaining self-management skills in chronic diseases(8, 9). To measure self-efficacy(10), we

administered the PROMIS® Self-Efficacy for Managing Chronic Conditions measure, which is comprised of 5 domains: Managing symptoms, Daily activities, Medications and treatments, Emotions, and Social interactions. Each domain consists of 8 items scored from 1 (not at all confident) to 5 (very confident), with higher scores indicative of greater self-efficacy. The scales were standardized to the US population so that the mean was 50 and the SD was 10 units, and results were scored using <u>http://www.healthmeasures.net/explore-measurement-</u> <u>systems/promis</u>. We used the domain for managing symptoms as **the primary outcome measure**.

The PROMIS-29 Profile v2.0<sup>°</sup> measure contains 29 items, one on pain intensity and 4 items in each of the following domains: physical function, anxiety, depression, fatigue, sleep disturbance, pain interference, and satisfaction with social roles(11). With the exception of physical function, which does not include a time frame, all item banks referenced the past 7 days. Items were scored from 1 (unable to do/never/not at all) to 5 (without any difficulty/always/very much). All scales, except the pain intensity item, were standardized to the US population so that the mean was 50 and SD was 10 units, and they were scored using <u>http://www.healthmeasures.net/explore-measurementsystems/promis</u>.

The Patient Health Questionnaire-8 (PHQ-8) is an 8-item questionnaire that is commonly used to measure depressive symptoms(12). A score of  $\geq$ 10 is consistent with depressed mood.

The Patient Activation Measure (PAM) is a 13-item measure that assesses patient knowledge, skill, and confidence for self-management(13). Each item is scored from 1 (strongly disagree) to 4 (strongly agree). Scores are then summed, yielding a total that can range in value from 13.0 to 52.0. The summed score is finally transformed into a 0- to 100-point scale with higher scores indicating more confidence and knowledge in patients managing their condition. PAM scores were categorized into 4 levels—Level 1: Individual is disengaged and overwhelmed; Level 2: Individual is aware but struggling; Level 3: Individual is taking action; and Level 4: Individual is maintaining behavior (<u>https://www.insigniahealth.com/products/pam-survey</u>). The PAM has been extensively used in different self-management courses(14).

The European Quality of Life-5 Dimensions (EQ-5D) and Quality Adjusted Life Years (QALYs) provides a generic health-related quality of life assessment. The EQ-5D incorporates patient-reported outcomes along the domains of mobility, self-care, activity, pain, and anxiety. 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).

The Brief Satisfaction with Appearance Scale (SWAP) is a 6-item scale measuring body image concerns and social discomfort with body parts. It is scored from 0 to 36, with higher scores associated with greater dissatisfaction.

Participants in *both* groups completed questionnaires at baseline and post-intervention at 16 weeks. A program evaluation was performed by asking participants in the intervention group to complete a questionnaire to gauge the content and presentation of the modules and to provide other feedback to the investigators.

#### Sample Size

Sample size calculation was based on an analysis of pre–post changes in the Chronic Disease Self-Efficacy Scale in our pilot internet study(5). Based on pilot data, we expected that the effect size (ES; mean pre–post change/SD at baseline) in the intervention group would be approximately 0.50 (medium effect size as suggested by Cohen(15), and we anticipated a negligible effect size in the control group (ES = 0.10). Using a significance level of .05, we estimated that recruiting 100 participants in each group would yield an 80% power for detecting this difference between the intervention and the control group. Assuming a conservative attrition rate of 25% during the study, we planned to enroll 125 patients in each group.

#### Randomization

Participants who met the inclusion criteria were sent instructions to review an electronic consent form through a Qualtrics<sup>®</sup> platform. Once signed consents were obtained, participants were invited to complete the baseline questionnaire. Participants who completed

the consent were randomized to either an intervention or control group. Randomization was performed using a 1:1 ratio and via computer-generated block randomization, with stratification based on the PHQ-8 score (respectively, <10,  $\geq$ 10) to ensure that subjects with depressive symptoms were equally distributed in the two groups. Stratification based on the PHQ-8 score was pursued because we hypothesized that participants who reported being depressed may have poor coping and self-management skills. Although the assignment to either group was random, to ensure that the proportion of patients with more or fewer depressive symptoms was approximately the same in both groups, after every 50 patients were recruited, the assignment of patients to each group up to that point was cross-tabulated with respect to PHQ-8 scores. In addition, block randomization of patients occurred in groups of 50. This allowed us to divide the intervention groups into 5 waves of 25 participants so that the Discussion board groups were small enough to encourage participation.

#### Intervention

Patients randomized to the internet program received a link to the self-management website, as well as a password and user name. The site could only be accessed via a secured website. The 15 modules including: Basic Overview, Coping and Body Image, Exercise, Self-Advocacy, Pain Management, Activities of Daily Living, Fatigue and Energy Conservation, Tips for Families and Caregivers, Muscle and Lung Disease with a focus on African Americans, Gastrointestinal Tract, Raynaud's Disease, Sexuality and Scleroderma, Mouth and Teeth Care, Clinical Trials, and Emergencies were presented with 1 module focus made available per week. Two investigators (JLP, SLN) posted weekly questions regarding the modules on the Discussion Board and moderated the online discussion as necessary (content is included as Appendix 1). Participants were asked to log on to the Discussion Board at least once weekly.

Those allocated to the control group received a copy of *The Scleroderma Book: A Guide for Patients and Families*, by Dr. Maureen Mayes. This book is the authoritative, educational book most requested and used by patients with a 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. Participants randomized to the control group were sent the textbook. The control group was given 16 weeks to read the book. A variety of strategies were used to maintain participant engagement in *both* groups during the intervention, including phone calls or email contact at 4-, 8-, and 12-weeks, and an incentive of \$150 in the form of gift cards during the course of the study.

#### Statistical analysis

Summary statistics of the baseline demographic variables were computed for all the patients enrolled in the study. For each of these variables, summary statistics were calculated for the group of patients as a whole, and stratified by treatment group (intervention vs. standard care). Group differences for these characteristics were tested using either t-tests, Wilcoxon tests, proportion test, or Chi-square tests, depending on the type of data (continuous vs. categorical, normally distributed vs. not).

To compare group differences between the intervention and control group postintervention, we considered only subjects with both baseline and follow-up data available. For those subjects, we computed the change in the scores from baseline to follow-up for continuous variables. For categorical variables, such as the PAM levels, we generated contingency tables presenting the joint distribution of the categorical classes at both baseline and follow-up (e.g. what percent of patients belonged to PAM level 1 at baseline and PAM level 1 at follow-up, and so forth). For both continuous and categorical variables, we tested whether there was a significant difference between the two groups either in the change in the scores or in the joint distributions of the categorical variables. Specifically, for continuous variables, we assessed whether there was a significant difference in the change in the scores in the control and internet groups by performing either t-tests, if the change in score appeared to be continuous and normally distributed, or Wilcoxon tests if a normal distribution did not seem appropriate. For categorical variables, we assessed whether there was a significant difference in the joint distribution of the categorical variable at baseline and follow-up in the two groups using Fisher's exact due to small counts in some of the contingency table cells. For each test, we used a significance level of 0.05 with no adjustment for multiple testing.

#### Results

A total of 267 subjects agreed to participate in the study and were randomized to either group. Of these 267 participants who completed baseline questionnaires and were randomized to the intervention (internet) or control (book) condition (**Figure 1**), 123 (93%) in the internet and 124 (94%) in the control completed the 16-week RCT. The two groups were similar at baseline with respect to the demographic variables (**Table 1**). Overall, the mean (SD) age was 53.7 (11.7) years, 91% were female, 82.8% were White, and 79.4% had some college or higher degree. The mean (SD) disease duration after diagnosis of SSc was 8.97 (8.50) years with 44.9% in the internet group and 43.1% in the control group, classifying themselves as limited/sine and diffuse SSc, respectively.

Regardless of group, participants had similar mean scores on PROs except for the EQ-5D VAS which showed statistically higher scores in the internet group (**Table 2**). For the PROMIS self-efficacy and PROMIS-29 measures, the scores ranged from being similar between groups (PROMIS Self Efficacy Managing Medications and Treatment) to being 1.00 SD below the mean US population (PROMIS-29 Physical function scale). The mean (SD) PHQ-8 score was 8.67 (5.18), and 43.1 % had depressed mood. Regarding the PAM scores, 18.7% and 59.6% were in PAM Level 3 and PAM Level 4, respectively.

Table 2 shows the mean change scores for the two groups between baseline and post intervention at 16 weeks for all variables. There were no statistical differences between the 2 groups for the primary outcome measure (PROMIS Self Efficacy Managing Symptoms: mean change of 0.35 in the internet group vs. 0.94 in control group, p=0.47) and other PROs, except for a significant difference between the internet and control groups for changes in the way the EQ-5D index changes from baseline to follow-up.

As we recruited a group of participants who had a high level of patient activation (approximately 60% had PAM Level 4), and long disease duration, we assessed the participants with early disease (<2 years and <5 years), PHQ< 10, PHQ≥10, and PAM Level 1 and 2 **(Table 3)**. Again, there were no differences between the two groups, except for PROMIS-Self Efficacy Managing Symptoms favoring the control group in early disease duration (p=0.03) (Table 4), and EQ-5D Self Care favoring the control group for those with  $PHQ \ge 10$  (p=0.02).

#### **Discussion Board Evaluation**

Of the 134 participants randomized to the internet group, 81 (61.4%) visited the discussion board, with 79 (59.8%) posting at least one comment over the 16-week RCT. An average of 8 comments were posted per user, with an average of 58.21 minutes reviewing each module. At the end of the 16-week RCT, 100 (74.6%) participants completed a course evaluation, in which they were asked to rate each module as helpful, slightly helpful, not helpful at all, or did not review this module (Appendix Figure 1). An average of 75.4% rated the modules as being helpful. Key modules, with over 60 hours of time spent on each module, included Scleroderma: A Basic Overview, Coping and Body Image/Appearance, Exercise, Self-Advocacy, and Dysphagia and the Digestive Tract. The course evaluation showed that 67.9% of participants agreed the Discussion Board addressed important issues about scleroderma, with 44.5% agreeing the Discussion Board increased their understanding of scleroderma, and 63.0% agreeing the Discussion Board was a good way to learn from people with scleroderma. When asked about their impression of the self-management course, an overwhelming 93.0% agreed that the modules were of importance to them; 94.0% agreed that the information was presented clearly with the website being easy to use, and at an appropriate reading level (Figure 2). We also provided access to the internet site for the participants who were randomized to the control group. 49 participants responded to the survey and 91.84 % agreed that the information was presented clearly and 93.75% agreed that the website was easy to use. AU<sup>+</sup>

Discussion

Using input from US Scleroderma Foundations and patient partners, we refined a previously developed internet program and tested it in the current RCT. Although we could not show any difference in the primary and secondary outcome measures, participants from the intervention showed overwhelming support and enthusiasm for the content and presentation on the website (Appendix **Figure 1**).

Based on input from the patient and stakeholder partners, we stratified the randomization with respect to PHQ-8 being below 10 vs. at least 10, as we hypothesized that participants who have depressed mood may exhibit poor coping skills. Although participants with PHQ-8 scores of  $\geq$  10 had lower scores on self-efficacy and PROMIS-29 scores (data not shown), there was no benefit in the internet group compared to control group. Our baseline data suggests that we recruited a group of highly motivated (approximately 60% had PAM Level 4), highly educated participants (80% had attended at least some college), who have been dealing with their disease for a long time (the mean time since diagnosis was 9 years). When we focused only on participants with early disease (<2 years and< 5 years), PHQ $\geq$ 10, and PAM Level 1 and 2, we found no difference between internet group vs. control group, although the sample sizes in these subgroups were very small and may be related to Type 2 error.

Patients with chronic diseases such as SSc make daily decisions or self-manage their illnesses. A central concept in self-management education is self-efficacy(16), which is a major determinant of behavior and behavioral change, and acts as a key mediator of the attainment of self-management skills in chronic diseases(8, 9). Published work suggests that self-management skills are associated with improved clinical outcomes, and reduce costs for arthritis(16).

Because SSc is a rare disease (designated as an orphan disease by the Food and Drug Administration), Scleroderma Foundation Chapters and/or support groups do not exist throughout every state in the United States. Many people with SSc have not met anyone with the disease(17, 18). Patients living outside major metropolitan areas may not have access to health care providers with a specialized knowledge of SSc. Thus, SSc patients feel isolated from sources of support and education programs. The only education programs specifically focused on scleroderma are offered via written materials, webinars and annual conferences through the Scleroderma Foundation, and state and/or local chapters of the Scleroderma Foundation and the Scleroderma Research Foundation. These offerings are credible sources of information, but patients may need to search through a website or wait for the next conference, meeting, or webinar. Having an internet program that contains all the information and resources on selfmanagement in one site and one format that can be quickly updated may be very useful to meet the needs of patients with scleroderma and their families and/or caregivers. Creators of the Arthritis Self-Management Program and Chronic Disease Self-Management Program developed internet versions of their successful programs, with outcomes similar to those achieved with the group format (19, 20). The advantages of internet programs are that they are easily accessible; can be shared with family members, caregivers, and/or health professionals; and can be viewed as many times as needed for reinforcement or as symptoms change with disease progression. However, the existing self-management programs for arthritis and chronic illness do not address the specific needs of scleroderma patients related to body image changes, skin and wound management, gastrointestinal involvement, lung involvement, Raynaud's phenomenon and ulcerations, and disability. This was exemplified by a recent study showing that information available on the internet is not meeting the health care needs of systemic scleroderma patients(21).

#### **Recommendations for future work**

Our study also provides insight into the design of the next trial. First, it highlights that the majority of the participants with SSc using the internet materials were well-educated, classified themselves as white, and were well-versed in management of their disease (approximately 80% had attended college or higher education, 83% were white, and 60% were in PAM Level 4). Future studies should focus on recruiting participants with lower PAM levels (likely to be non-white and less educated participants) who have lower self-efficacy scores(10), and who would likely benefit from self-management courses. Second, participants with earlier disease may benefit, as published data suggests that patients' adjustment to a chronic disease improves with time(22). Our RCT has many strengths. We recruited and retained over 90% of participants over a period of 16 weeks. In addition, we collaborated with patient partners and stakeholders and recruited participants from both academic and non-academic settings, providing generalizability for our results. Lastly, this is one of the largest studies evaluating a self-management or behavioral intervention in people with SSc.

In conclusion, our RCT showed that the internet-based self-management website was not superior to the patient-focused textbook in improving self-efficacy and other measures. High patient activation scores and near normal self-efficacy scores may have contributed to this result. However, participants were overwhelmingly enthusiastic, indicating a need for an internet program that is credible and easily accessible.

#### Funding

Research reported in this publication was partially funded through a Patient-Centered Outcomes Research Institute (PCORI) Award (CER-1310-08323). The statements presented in this publication are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute (PCORI), its Board of Governors, or its Methodology Committee. Dr. Khanna was also supported by the NIH/ NIAMS K24.

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#### **Appendix 1 Discussion Board Questions**

#### Module 1 Scleroderma: A Basic Overview

Please take the time to do the worksheets for Module 1 and think about how your scleroderma affects your body. Are there any surprises? Are there things that you want to talk over with the rheumatologist that you had not thought about before? Are you doing better than you thought? Is your scleroderma more comprehensive than you thought? Although the disease can seem scary, the more that you know the more prepared you are to take charge of your illness and your life.

#### Module 2 Self-Advocacy

As indicated in the module, advocacy can take many forms. We provided worksheets to help you get started.

Do you advocate for yourself? Can you share an experience?

If you have not advocated for yourself in the past, or have found it uncomfortable to do so, do you think you can now start to take small steps to do so? How do you think you will start?

#### Module 3: Exercises

Please share your experiences with stretching and exercising.

If you had not been exercising before you started the program, please try to slowly work through the exercises in module three - only to the extent that your capable and share your experiences over the period of the program.

Do you feel your tolerance for exercising increasing?

Are you able to increase your stretch as you continue in the program?

Are you having problems completing any of the exercises?

#### Module 4 - Coping and body image:

Any chronic illness can challenge your coping skills. The body changes that often come with scleroderma can be especially difficult. The coping and body image module discussed several strategies to manage changes in body image and the stresses associated with any chronic illness, and especially the unique challenges presented by scleroderma.

Have you used any of strategies suggested in the coping body image module?

If not, do you think that some of these strategies could be helpful to you?

What strategies have you used that have helped you manage the stresses of scleroderma and the changes in appearance that can come with the disease?

#### Module 5 Fatigue and Energy Conservation

Module 5 covers management of fatigue. Fatigue can be a serious problem in Scleroderma. Energy conservation includes big things, like giving up tasks (not vacuuming) and small things (using bag lettuce). Why don't we use this thread to discuss energy conservation strategies at home, work or school

This might also be a good place to think about how to use advocacy skills to get the necessary help to conserve energy.

#### Module 6 Raynaud's Phenomenon, Finger Ulcers, Calcinosis, and Skin Involvement

Module 6 discusses skin problems, ulcers and Raynaud's Phenomenon.

Almost everyone with Scleroderma has Raynaud's Phenomena. What strategies have you used to manage your hands, and the other parts of your body where you experience Raynaud's?

#### Module 7 Gastrointestinal Tract

As you read through module 7 you probably realized that scleroderma can affect the GI system in a variety of ways. Some of you may have GI symptoms, some of you may not experience any symptoms in the GI tract.

As we have in the other module I think it is valuable to talk about what has worked.

How have those of you who have GI symptoms managed those symptoms. Were there strategies in the module that you had not previously tried that were useful to you?

#### Module 8 Muscle and Lung Disease with a focus on African Americans

Probably one of the most important pieces of information to get from this module is to make sure you know what antibodies you have regardless of your race and/or ethnicity.

Do you know your antibodies?

If you have muscle or lung involvement, how are you managing and how are you monitoring these?

#### Module 9 Activities of Daily Living

Because Scleroderma can affect each person so differently, it can influence activities of daily living differently. What challenges have you experienced and how have you dealt with those challenges? Have you

#### **Module 10 Mouth and Teeth Care**

If you are having difficulty opening your mouth it can be difficult to take care of your teeth.

We have suggested some stretching exercises to help stretch the mouth area. What have your experiences been with these exercises?

What are your tips, suggestions or struggles with mouth care?

#### Module 11 Pain Management

As stated in the module pain can be a major problem in people who have diseases such as scleroderma. Pain can also affect all areas of one life. Have you tried any of the ideas in the modules? Do they work for you? What other strategies have you found to be successful in managing pain?

#### Module 12 Sexuality and scleroderma

As the module stated, sexuality is often not discussed between health professionals and patients. Sexuality is often the ignored activity of daily living. Hopefully, the module has answered some questions and maybe raised new ones.

What did you learn from the module that you did not know before?

What suggestions have you tried or do you think you will try?

What unanswered questions do you have?

#### **Module 13 Emergencies**

Module 13 included information about some of the medical emergencies that can occur with Scleroderma.

Part of preparing for an emergency is not only knowing the symptoms of the medical emergency but knowing that you can leave your home to attend to your health and that matters of your home will be okay.

How prepared are you if you do indeed have an emergency?

Do you have an emergency plan? If you do, could you share some of your plan?

What are some of the things that you are doing to start making an emergency plan for your home/family?

#### Module 14 Tips for caregivers

We hope you learned a lot from module 14 and encourage you to share this module with your caregiver, family and/or friends. Although it is written for the caregiver/family, understanding and communicating is key.

What tips did you learn about or what tips are you already using to work and communicate with your caregiver/family?

Was the module helpful in understanding the caregiver/family perspective?

#### Module 15 Clinical Trials

Module 15 discussed clinical trials and advantage and disadvantages of participating in them. It is helpful to know what trials are being done and how to find them.

This week I have a "homework" assignment. Use the instructions on basic steps to use the clinicaltrials.gov website and go into clinicaltrials.gov and see if you can find the trial for this study. Then see what other studies are available for people with systemic sclerosis/scleroderma.

What other studies are available? Do you see any you might be interested in?

Do you have any unanswered questions about clinical trials?

Author M

	Values	Intervention	Control	n velve
Variable	(n=267)	(n=134)	(n=133)	p-value
Age Mean± SD (yrs)	53.7 (11.7)	54.3 (10.1)	52.9 (13.1)	0.33
Female Sex, no.(%) (n )	91 (243)	91.8 (123)	90.2 ( 120)	0.82
Race, no.% (n )				
White 🔵	82.8 (221)	83.6 (112)	82.0 (109)	0.85
African American	7.5(20)	5.2 (7)	9.8 (13)	0.24
Asian/Asian American	1.5 (4)	0.7 (1)	2.3 (3)	0.61
Native Hawaiian or Other Pacific Islander	0.7 (2)	1.5 (2)	0	0.48
Other	1.5 (4)	0.7 (1)	2.25 (3)	1
Multiracial	6(16)	8.2 (11)	3.8 (5)	0.2
Ethnicity % (n )				
Hispanic	4.1 (11)	5.2 (7)	3.0 (4)	0.55
Non-Hispanic	77.5 (207)	78.4 (105)	76.7 (102)	0.86
Other	15 (40)	14.9 (20)	15.0 (20)	1
Unknown	3.4(9)	1.5 (2)	5.3 (7)	0.17
Education % (n )				
High school ( 9-12)	20.6 (55)	20.1 (27)	21.1 (28)	0.98

Table 1 Baseline characteristics of participants in the randomized clinical trial

College/University (13-16)	48.3 (129)	49.3 (66)	47.4 (63)	0.85
Graduate School (17-22)	27 (72)	26.9 (36)	27.1 (36)	1
Post Graduate School ( 23+)	4.1 (11)	3.7 (5)	4.5 (6)	0.99
Marital Status % (n)				
Single, never married	11.6 (31)	7.5 (10)	15.8 (21)	0.05
Married	63.7 (170)	70.9 (95)	56.4 (75)	0.02
Widowed	3.4 (9)	1.5 (2)	5.3 (7)	0.17
Divorced/Separated	21.3 (57)	20.1 (27)	22.6 (30)	0.74
Employment status % (n)				
Working full time (20 hours or more per				
wk.)	35.6 (95)	35.8 (48)	35.3 (47)	1
Working part time (less than 20 hours per				
wk.)	6.7 (18)	7.5 (10)	6.0 (8)	0.82
On disability or sick leave	26.2 (70)	23.9 (32)	28.6 (38)	0.46
Retired	22.1 (59)	23.9 (32)	20.3 (27)	0.58
Not working but looking for work	2.3 (6)	1.5 (2)	3.0 (4)	0.67
Other	7.1(19)	7.5 (10)	6.8 (9)	1
Self-defined scleroderma sub type % (n )				
Limited/Sine %	44.9(120)	42.5 (57)	47.4 (63)	0.5
Diffuse %	43.1 (115)	42.5 (57)	43.6 (58)	0.96
Overlap %	11.6 (31)	14.1 (19)	9.0 (12)	0.26

Unknown	0.4 (1)	0.7 (1)	0	1
Patient-Reported Disease duration, Mean±				
SD (yrs)				
After First Diagnosis from Doctor	8.97 (8.50)	8.72 (7.81)	9.23 (9.17)	0.63
After First Scleroderma Symptoms	11.91 (10.10)	12.20 (9.33)	11.62 (10.84)	0.64
Overall health % (n)				
Excellent	1.1 (3)	0.7 (1)	1.5 (2)	1
Very Good	12.4 (33)	12.7 (17)	12.0 (16)	1
Good	42.7 (114)	44.8 (60)	40.6 (54)	0.57
Fair	37.4 (100)	34.3 (46)	40.6 (54)	0.35
Poor	6.4 (17)	7.5 (10)	5.3 (7)	0.63
U.S. geographical region % (n)				
Midwest	50.2 (134)	54.5 (73)	45.9 (61)	0.2
Northeast	8.6 (23)	5.2 (7)	12.0 (16)	0.08
South	20.6 (55)	20.9 (28)	20.3 (27)	1
West	20.6 (55)	19.4 (26)	21.8 (29)	0.74

	Μ	lean Patient-Repo	orted Outcomes Base	line compared to	16 weeks		
Scales	BA	ASELINE	10	6 WEEKS	C	CHANGE	
	Internet group	Control Group	p-value Internet group	Control group	p-value Internet group	Control group	p-value
PROMIS Self-							
Efficacy							
Managing	Mean=46.78	Mean=46.34	Mean=46.6	Mean=47.20 S	Mean=0.09	Mean=0.73	
Emotions	SD=9.29 N=133	SD=8.75 N=133	0.69SD=9.20 N=123	D=9.33 N=124	0.62SD=6.28 N=122	SD=5.34 N=124	0.29
C						Mean=0.94;	
Managing	Mean=47.41;	Mean=47.58;	Mean=47.53;	Mean=48.61;	Mean=0.35;	SD=6.79;	
Symptoms	SD=9.15; N=134	SD=7.81; N=133	0.87SD=8.50; N=123	SD=8.70; N=124	0.32SD=6.12; N=123	3N=124	0.47
						Mean=0.79;	
Managing Daily	Mean=44.83;	Mean=44.71;	Mean=45.18;	Mean=45.37;	Mean=0.17;	SD=4.52;	
Activities	SD=7.60; N=134	SD=6.77; N=133	0.89SD=7.84; N=123	SD=7.70; N=124	0.85SD=5.11; N=123	3N=124	0.32
						Mean=0.99;	
Managing Social	Mean=46.57;	Mean=46.66;	Mean=46.91;	Mean=47.43;	Mean=0.43;	SD=7.42;	
Interactions	SD=9.74; N=134	SD=8.96; N=133	0.93SD=9.63; N=123	SD=9.50; N=124	0.67SD=6.94; N=123	3N=124	0.54
Managing Meds	Mean=49.15;	Mean=50.3;	Mean=49.0;	Mean=50.85;	Mean=-0.54;	Mean=0.70;	
and Treatment	SD=9.06; N=134	SD=8.29; N=133	0.28SD=8.99; N=123	SD=9.28; N=124	0.05SD=7.59; N=123	3SD=6.29;	0.16

#### Table 2. Mean Patient-Reported Outcomes at Baseline, 16 weeks, and changes score over 16 weeks

5						Mean=0.75;	
Physical Function	nMean=40.63;	Mean=40.17;	Mean=40.81;	Mean=40.86;	Mean=0.05;	SD=4.83;	
	Sd=6.95; N=134	SD=6.15; N=133	0.59SD=8.14; N=123	SD=7.30; N=124	0.96SD=5.71; N=123	N=124	0.25
0					Mean=2.05;	Mean=2.24;	
Social Role	Mean=43.74;	Mean=44.39;	Mean=45.82;	Mean=46.68;	SD=17.19;	SD=15.58;	
	SD=8.63; N=134	SD=7.68; N=133	0.51SD=9.46; N=123	SD=8.86; N=124	0.46N=123	N=124	0.93
		Mean=54.11;	Mean=54.14;	Mean=53.06;		Mean=-0.86;	
Anxiety	Mean=53.85;	SD=10.31;	SD=10.25;	SD=10.11;	Mean=0.16;	SD=7.64;	
	SD=9.72; N=134	N=133	0.83N=123	N=124	0.41SD=6.93; N=123	N=124	0.27
	Mean=51.04;					Mean=-0.13;	
Depression	SD=10.03;	Mean=51.59;	Mean=51.29;	Mean=51.22;	Mean=0.08;	SD=6.76;	
	N=134	SD=9.69; N=133	0.64SD=9.53; N=123	SD=9.70; N=123	0.96SD=6.40; N=123	N=124	0.8
0	Mean=58.47;	Mean=58.91;	Mean=58.06;	Mean=59.24;		Mean=0.20;	
Fatigue	SD=10.52;	SD=10.31;	SD=10.59;	SD=10.96;	Mean=-0.005;	SD=7.19;	
+	N=134	N=133	0.73N=123	N=123	0.67SD=6.90; N=123	N=124	0.82
Pain						Mean=-0.80;	
Interference	Mean=57.99;	Mean=57.92;	Mean=57.09;	Mean=57.37;	Mean=-0.65;	SD=6.95;	
interrence	SD=9.37; N=134	SD=9.22; N=133	0.95SD=9.20; N=123	SD=9.50; N=124	1 SD=6.96; N=123	N=124	0.87
VAS Pain	Mean=4.08;	Mean=4.25;	0.65Mean=4.13;	Mean=4.14;	0.98Mean=0.11;	Mean=-0.19;	0.19

PROMIS-29

Intensity	SD=2.21; N=134	SD=2.26; N=133	SD=2.29; N=123	SD=2.26; N=124	SD=1.78; N=123	SD=1.78;	
						N=124	
						Mean=-3.40;	
Sleep	Mean=55.22;	Mean=56.18;	Mean=52.08;	Mean=52.80;	Mean=-2.95;	SD=6.62;	
Disturbance	SD=6.96; N=134	SD=7.84; N=133	0.29SD=7.28; N=123	SD=7.91; N=124	0.46SD=6.22; N=123	N=124	0.58
C						Mean=-1.27;	
рнд-8	Mean=8.61;	Mean=8.72;	Mean=7.44;	Mean=7.40;	Mean=-1.19;	SD=4.99;	
	SD=5.39; N=134	SD=4.98; N=133	0.87SD=5.56; N=123	SD=5.65; N=124	0.96SD=5.02; N=123	N=124	0.89
EQ-5D							
						Mean=0.01;	
Mobility	Mean=1.53;	Mean=1.61;	Mean=1.54;	Mean=1.63;	Mean=0.0;	SD=0.47;	
$\leq$	SD=0.52; N=134	SD=0.49; N=133	0.18SD=0.50; N=123	SD=0.49; N=124	0.14SD=0.48; N=123	N=124	0.89
						Mean=-0.02;	
Self-Care	Mean=1.28;	Mean=1.35;	Mean=1.33;	Mean=1.32;	Mean=0.04;	SD=0.37;	
0	SD=0.48; N=134	SD=0.49; N=133	0.19SD=0.51; N=123	SD=0.49; N=124	0.93SD=0.41; N=123	N=124	0.13
						Mean=-0.02;	
Usual Activities	Mean=1.78;	Mean=1.79;	Mean=1.78;	Mean=1.77;	Mean=0.01;	SD=0.38;	
	SD=0.50; N=134	SD=0.43; N=133	0.82SD=0.54; N=123	SD=0.46; N=124	0.94SD=0.47; N=123	N=124	0.76
						Mean=-0.06;	
Pain Discomfort	Mean=1.93;	Mean=2.02;	Mean=1.93;	Mean=1.96;	Mean=0.03;	SD=0.44;	
	SD=0.48; N=134	SD=0.43; N=133	0.11SD=0.43; N=123	SD=0.45; N=124	0.57SD=0.44; N=123	N=124	0.08

								Mean=-0.05;	
Anxiety	Mean=1.56;	Mean=1.63;		Mean=1.57;	Mean=1.57;		Mean=0.02;	SD=0.51;	
t	SD=0.61; N=134	SD=0.62; N=133	0.34	4SD=0.57; N=123	SD=0.63; N=124	0.8	7SD=0.47; N=123	3N=124	0.19
	Mean=67.47;	Mean=63.72;		Mean=68.28;	Mean=64.92;		Mean=0.37;	Mean=1.40;	
VAS	SD=18.01;	SD=17.33;		SD=18.61;	SD=19.13;		SD=16.39;	SD=16.57;	
<b>O</b>	N=134	N=133	0.05	5N=123	N=124	0.14	4N=123	N=124	0.62
S								Mean=0.02;	
EQ-5D Index	Mean=0.71;	Mean=0.69;		Mean=0.72;	Mean=0.71;		Mean=-0.002;	SD=0.14;	
2	SD=0.18; N=134	SD=0.16; N=133	0.08	3SD=0.17; N=123	SD=0.17; N=124	0.6	9SD=0.14; N=123	3N=124	0.05
							Mean=-0.82;	Mean=-0.31;	
SWAP	Mean=17.1;	Mean=16.81;		Mean=16.47;	Mean=16.76;		SD=10.58;	SD=9.56;	
$\leq$	SD=9.53; N=134	SD=8.13; N=133	0.96	5SD=9.47; N=123	SD=9.08; N=124	0.8	1N=123	N=124	0.69
Patient									
Activation									
Measure (PAM)									
PAM									
Level 1,									
N (%)	14 (10.45)	14 (10.53)	1	10 (8.13)	12 (9.68)	0.8	2 NA	NA	
PAM									
Level 2,	15 (11.19)	15 (11.28)	1	13 (10.57)	13 (10.48)	1	NA	NA	

N (%)							
PAM							
Level 3,							
N (%)	23 (17.16)	27 (20.30)	0.5326 (21.14)	22 (17.74)	0.52	NA	NA
РАМ							
Level 4, 💙							
N (%)	82 (61.19)	77 (57.89)	0.6274 (60.16)	77 (62.10)	0.79	NA	NA
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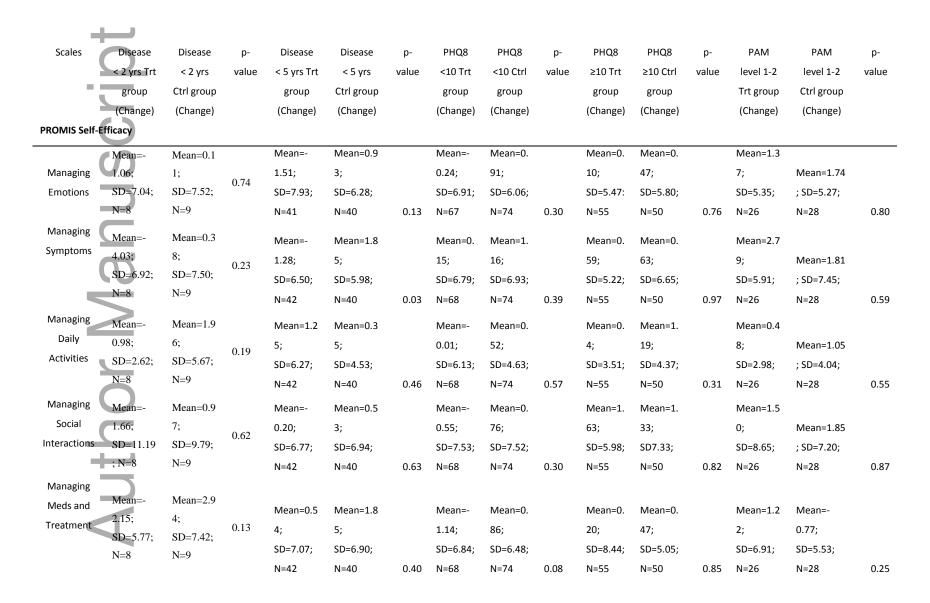
Scales	Disease	Disease	p-	Disease	Disease	p-	PHQ8	PHQ8	p-	PHQ8	PHQ8	p-	PAM	PAM	p-
	< 2 yrs Trt	< 2 yrs Ctrl	valu	< 5 yrs Trt	< 5 yrs Ctrl	valu	<10 Trt	<10 Ctrl	valu	≥10 Trt	≥10 Ctrl	valu	level 1-2	level 1-2	valu
	group	group	е	group	group	е	group	group	е	group	group	е	Trt group	Ctrl group	е
	(Baseline)	(Baseline)		(Baseline)	(Baseline)		(Baseline)	(Baseline)		(Baseline)	(Baseline)		(Baseline)	(Baseline)	
PROMIS Sel	lf-Efficacy														
	()	Mean=44.0		Mean=49.2	Mean=46.1					Mean=43.4	Mean=44.3		Mean=39.5	Mean=40.5	
Managing	Mean=46.8	6;		6;	4;		Mean=49.4	Mean=47.5		5;	3;		5;	3;	
Emotions	0; SD=9.25;	SD=10.24;		SD=10.33;	SD=8.37;		7; SD=8.29;	9; SD=8.58;		SD=9.76;	SD=9.00;		SD=7.31;	SD=6.74;	
	N=8	N=12	0.54	N=41	N=40	0.14	N=72	N=79	0.17	N=55	N=50	0.63	N=26	N=28	0.61
Managing	Mean=49.9														
Symptoms	6;	Mean=47.5		Mean=50.3	Mean=47.1		Mean=49.8	Mean=48.0		Mean=44.2	Mean=46.8		Mean=39.0	Mean=42.2	
	o, SD=10.72;	1; SD=5.51;		2;	5;		1; SD=8.44;	4; SD=7.89;		8;	6;		6;	5;	
	SD=10.72, N=8	1, 3D-3.31, N=12	0.56	SD=9.25;	SD=7.05;	0.08	1, 3D-8.44, N=73	4, 3D-7.89, N=79	0.18	SD=9.05;	SD=7.97;	0.12	SD=6.09;	SD=6.08;	0.06
Managing		N-12	0.50	N=42	N=40	0.08	N-75	N-79	0.18	N=55	N=50	0.12	N=26	N=28	0.00
Managing				Mean=46.5	Mean=44.5					Mean=42.7	Mean=42.7		Mean=40.0	Mean=42.2	
Daily	Mean=46.1	Mean=43.1		3;	2;		Mean=46.5	Mean=45.8		7;	9;		5;	2;	
Activities	1; SD=7.84;	6; SD=4.48;		SD=7.77;	SD=6.04;		9; SD=7.93;	7; SD=7.37;		SD=6.40;	SD=5.38;		SD=5.74;	SD=6.41;	
	N=8	N=12	0.36	N=42	N=40	0.19	N=73	N=79	0.56	N=55	N=50	0.99	N=26	N=28	0.20
Managing				Mean=49.1	Mean=47.0					Mean=43.1	Mean=45.9		Mean=38.7	Mean=39.9	
Social	Mean=47.3	Mean=47.1		0;	1;		Mean=49.3	Mean=46.6		3;	3;		6;	9;	
Interactio	1; SD=7.28;	8; SD=8.54;		SD=9.90;	SD=8.32;		3; SD=9.38;	1; SD=9.22;		SD=9.30;	SD=8.34;		SD=7.26;	SD=5.33;	
ns	N=8	N=12	0.97	N=42	N=40	0.3	N=73	N=79	0.07	N=55	N=50	0.11	N=26	N=28	0.48
Managing															
Meds and	-			M 50.2	M 40.5					M 47.0	M 49.9		12.0	NA 45.0	
Treatment	Mean=53.6	Mean=50.5		Mean=50.2 3;	Mean=49.5 3;		Mean=50.9	Mean=50.9		Mean=47.0 7;	Mean=48.8 8;		Mean=42.0 1;	Mean=45.2 9;	
	2; SD=5.08;	8; SD=7.48;		3; SD=9.45;	3; SD=8.41;		2; SD=8.64;	4; SD=7.97;		7; SD=9.30;	8; SD=8.76;		1; SD=6.52;	9; SD=8.50;	
	N=8	N=12	0.29	SD=9.43, N=42	SD=8.41, N=40	0.72	N=73	ч, <i>3D=7.37</i> , N=79	0.99	SD=9.50, N=55	SD=8.70, N=50	0.31	SD=0.52, N=26	N=28	0.12
PROMIS-29		.,	0.25	11-72	11-10	0.72			0.55	11-55	11-50	0.51	11-20	11-20	0.12
Physical	Mean=43.7	Mean=38.9	0.19	Mean=43.2	Mean=39.9	0.04	Mean=42.0	Mean=41.2	0.52	Mean=38.9	Mean=38.4	0.65	Mean=36.1	Mean=37.0	0.61
,															

#### Table 3 Mean Patient-Reported Outcomes Disease Duration, PHQ-8, and PAM Levels at Baseline

Function	9; SD=8.95;	2; SD=5.06;		6;	8;		4; SD=8.17;	8; SD=6.28;		5;	; SD=5.64;		8;	; SD=6.43;	
	N=8	N=12		SD=8.05;	SD=5.96;		N=73	N=79		SD=6.57;	N=50		SD=5.38;	N=28	
				N=42	N=40					N=55			N=26		
Social Role				Mean=41.4	Mean=44.4					Mean=46.5	Mean=46.4		Mean=50.6	Mean=47.8	
	Mean=41.5	Mean=46.7		0;	4;		Mean=41.5	Mean=43.1		1;	6;		3;	4;	
	6; SD=9.64;	8; SD=6.53;		SD=8.00;	SD=8.22;		2; SD=7.80;	9; SD=7.28;		SD=8.88;	SD=8.03;		SD=8.70;	SD=9.68;	
	N=8	N=12	0.21	N=42	N=40	0.09	N=73	N=79	0.18	N=55	N=50	0.98	N=26	N=28	0.27
Anxiety				Mean=52.8	Mean=53.9					Mean=57.9	Mean=58.5		Mean=59.7	Mean=61.6	
	Mean=56.1	Mean=58.3		6;	8;		Mean=50.5	Mean=51.3		3;	2;		2;	8;	
	8; SD=9.54;	8; SD=9.10;		SD=10.29;	SD=9.14;		3; SD=8.16;	9; SD=8.86;		SD=10.23;	SD=11.17;		SD=9.07;	SD=9.03;	
	N=8	N=12	0.61	N=42	N=40	0.6	N=73	N=79	0.53	N=55	N=50	0.78	N=26	N=28	0.43
Depressio	Mean=52.3	Mean=54.9		Mean=49.8	Mean=50.7					Mean=55.1	Mean=55.9		Mean=58.8	Mean=58.2	
n	4;	5;		7;	6;		Mean=47.7	Mean=48.8		4;	8;		8;	3;	
	SD=10.14;	SD=11.60;		SD=9.36;	SD=10.21;		6; SD=7.79;	; SD=8.01;		SD=11.21;	SD=10.73;		SD=10.31;	SD=7.87;	
	N=8	N=12	0.60	N=42	N=40	0.68	N=73	N=79	0.42	N=55	N=50	0.69	N=26	N=28	0.8
Fatigue	Mean=57.8			Mean=54.8	Mean=60.3		Mean=55.2			Mean=62.1	Mean=62.0		Mean=63.2	Mean=64.3	
_	9;	Mean=61.9		2;	3;		2;	Mean=56.7		1;	4;		1;	1;	
	SD=12.33;	1; SD=9.46;		SD=10.53;	SD=8.81;		SD=10.27;	7; SD=9.51;		SD=9.67;	SD=10.74;		SD=7.79;	SD=9.06;	
	N=8	N=12	0.45	N=42	N=40	0.01	N=73	N=79	0.34	N=55	N=50	0.97	N=26	N=28	0.63
Pain	Mean=59.6			Mean=55.6	Mean=57.4					Mean=60.5	Mean=60.4		Mean=62.4	Mean=62.4	
Interferen	9;	Mean=59.5		2;	7;		Mean=55.8	Mean=56.5		5;	0;		1;	5;	
ce	SD=12.28;	5; SD=7.92;		SD=10.06;	SD=9.33;		5; SD=8.59;	1; SD=9.34;		SD=9.72;	SD=8.62;		SD=8.61;	SD=8.65;	
	N=8	N=12	0.98	N=42	N=40	0.39	N=73	N=79	0.65	N=55	N=50	0.93	N=26	N=28	1.0
VAS Pain	Mean=4.63	Mean=4.83		Mean=4.05	Mean=4.35		Mean=3.67	Mean=3.91		Mean=3.78	Mean=4.1;		Mean=4.27	Mean=4.21	
Intensity	; SD=2.72;	; SD=2.29;		; SD=2.12;	; SD=1.89;		; SD=2.08;	; SD=2.23;		; SD=1.93;	SD=2.28;		; SD=1.61;	; SD=1.99;	
	N=8	N=12	0.86	N=42	N=40	0.5	N=73	N=79	0.49	N=55	N=50	0.44	N=26	N=28	0.91
Sleep				Mean=54.5	Mean=56.0					Mean=56.9	Mean=57.5		Mean=58.0	Mean=59.8	
Disturban	Mean=56.2	Mean=57.0		3;	2;		Mean=53.6	Mean=55.0		5;	9;		9;	9;	
ce	1; SD=6.49;	4; SD=8.33;		SD=7.47;	SD=8.41;		3; SD=7.12;	8; SD=7.51;		SD=6.20;	SD=7.90;		SD=6.25;	SD=6.56;	
	N=8	N=12	0.81	N=42	N=40	0.4	N=73	N=79	0.22	N=55	N=50	0.65	N=26	N=28	0.31
PHQ- 8	Mean=11.6	Mean=10.4		Mean=9.26	Mean=8.80		Mean=4.49	Mean=5.35		Mean=13.7	Mean=13.6		Mean=11.5	Mean=11.5	
	2; Sd=3.62;	2; SD=5.26;	0.55	; SD=5.43;	; SD=5.40;	0.7	; SD=2.74;	; SD=2.55;	0.05	6;	2;	0.82	4;	7;	0.98

	N=8	N=12		N=42	N=40		N=73	N=79		SD=3.23;	SD=3.33;		SD=6.33;	SD=5.55;	
										N=55	N=50		N=26	N=28	
EQ-5D															
Mobility	Mean=1.5;	Mean=1.42		Mean=1.45	Mean=1.45		Mean=1.48	Mean=1.54		Mean=1.62	Mean=1.72		Mean=1.89	Mean=1.75	
	SD=0.53;	; SD=0.51;		; SD=0.50;	; SD=0.50;		; SD=0.50;	; SD=0.50;		; SD=0.53;	; SD=0.45;		; SD=0.33;	; SD=0.44;	
	N=8	N=12	0.75	N=42	N=40	0.99	N=73	N=79	0.43	N=55	N=50	0.26	N=26	N=28	0.21
Self-Care	Mean=1.38	Mean=1.25		Mean=1.31	Mean=1.35		Mean=1.22	Mean=1.30		Mean=1.36	Mean=1.42		Mean=1.65	Mean=1.5;	
	; SD=0.52;	; SD=0.45;		; SD=0.52;	; SD=0.48;		; SD=0.45;	; SD=0.49;		; SD=0.52;	; SD=0.50;		; SD=0.63;	SD=0.51;	
	N=8	N=12	0.59	N=42	N=40	0.59	N=73	N=79	0.23	N=55	N=50	0.49	N=26	N=28	0.41
Usual	Mean=1.75	Mean=1.83		Mean=1.76	Mean=1.83		Mean=1.75	Mean=1.76		Mean=1.82	Mean=1.84		Mean=2.0;	Mean=1.93	
Activities	; SD=0.89;	; SD=0.39;		; SD=0.58;	; SD=0.45;		; SD=0.50;	; SD=0.43;		; SD=0.51;	; SD=0.42;		SD=0.4;	; SD=0.38;	
	N=8	N=12	0.63	N=42	N=40	0.5	N=73	N=79	0.86	N=55	N=50	0.76	N=26	N=28	0.51
Pain	Mean=1.88	Mean=2.08		Mean=1.79	Mean=2;		Mean=1.88	Mean=1.99		Mean=1.96	Mean=2.08		Mean=2.08	Mean=2.14	
Discomfor	; SD=0.64;	; SD=0.51;		; SD=0.52;	SD=0.39;		; SD=0.47;	; SD=0.38;		; SD=0.47;	; SD=0.49;		; SD=0.27;	; SD=0.45;	
t	N=8	N=12	0.44	N=42	N=40	0.04	N=73	N=79	0.10	N=55	N=50	0.22	N=26	N=28	0.49
Anxiety	Mean=1.75	Mean=2;		Mean=1.52	Mean=1.63		Mean=1.43	Mean=1.49		Mean=1.71	Mean=1.84		Mean=1.89	Mean=2.0;	
1	; SD=0.70;	SD=0.60;		; SD=0.67;	; SD=0.59;		; SD=0.52;	; SD=0.55;		; SD=0.69;	; SD=0.68;		; SD=0.65;	SD=0.61;	
	N=8	N=12	0.40	N=42	N=40	0.33	N=73	N=79	0.45	N=55	N=50	0.31	N=26	N=28	0.50
VAS		Mean=58.2		Mean=70.8	Mean=63.8					Mean=62.8	Mean=56.6		Mean=57.3	Mean=57.5	
	Mean=62.0	5;		8;	5;		Mean=71.6	Mean=71.6		9;	6;		1;	;	
	; SD=20.99;	SD=21.83;		SD=17.85;	SD=18.67;		; SD=16.95;	; SD=15.63;		N=18.90;	SD=18.06;		SD=16.12;	SD=18.88;	
	N=8	N=12	0.91	N=42	N=40	0.09	N=73	N=79	0.10	N=55	N=50	0.09	N=26	N=28	0.97
EQ-5D	Mean=0.68	Mean=0.64		Mean=0.74	Mean=0.70		Mean=0.75	Mean=0.72		Mean=0.67	Mean=0.63		Mean=0.59	Mean=0.60	
Index	; SD=0.26;	; SD=0.18;		; SD=0.20;	; SD=0.14;		; SD=0.15;	; SD=0.13;		; SD=0.20;	; SD=0.19;		; SD=0.16;	; SD=0.19;	
1	N=8	N=12	0.51	N=42	N=40	0.09	N=73	N=79	0.06	N=55	N=50	0.30	N=26	N=28	0.83
Patient Act	tivation Measur	e (PAM)													
Mean					Mean=41.5					Mean=42.2	Mean=42.5		Mean=34.8	Mean=34.8	
PAM Raw	Mean=43.8	Mean=40.9		Mean=45.0	8;		Mean=44.7	Mean=43.7		5;	0;		8;	2;	
Score	8; SD=4.85;	2; SD=5.96;		; SD=5.22;	SD=5.99;	0.00	7; SD=5.16;	2; SD=5.54;		SD=6.75;	SD=5.98;		SD=3.15;	SD=2.68;	
	N=8	N=12	0.28	N=42	N=40	7	N=73	N=79	0.23	N=55	N=50	0.84	N=26	N=28	0.94
Mean	Mean=69.8	Mean=62.9		Mean=73.9	Mean=64.1	0.00	Mean=73.2	Mean=70.3		Mean=66.8	Mean=66.5		Mean=46.0	Mean=45.6	
PAM	9;	6;	0.28	5;	4;	8	1;	6;	0.26	8;	6;	0.93	7;	; SD=4.91;	0.76

Activation	SD=13.92;	SD=17.14;		SD=15.92;	SD=16.57;		SD=15.24;	SD=15.70;		SD=19.04;	SD=16.70;		SD=5.96;	N=28	
Score	N=8	N=12		N=42	N=40		N=73	N=79		N=55	N=50		N=26		
PAM Level							N=3	N=7							
1, N (%)	0 (0%)	2 (16.67%)	0.49	2 (4.76)	8 (20%)	0.05	(4.11%)	(8.86%)	0.33	10 (18.18)	7 (14.0)	0.61	12 (46.15)	14 (50.0)	0.79
PAM Level							N=8	N=6							
2, N (%)	2 (25.0%)	2 (16.67%)	1.0	4 (9.52)	5 (12.5)	0.73	(10.96%)	(7.59%)	0.58	6 (10.91)	8 (16.0)	0.57	14 (53.85)	14 (50.0)	0.79
PAM Level							N=11	N=18							
3, N (%)	1 (12.5%)	4 (33.33%)	0.6	6 (14.29)	10 (25.0)	0.27	(15.07%)	(22.78%)	0.30	10 (18.18)	8 (16.0)	0.8	0	0	1.0
PAM Level	$\mathbf{O}$						N=51	N=48							
4, N (%)	5 (62.5%)	4 (33.33%)	0.36	30 (71.43)	17 (42.5)	0.01	(69.86%)	(60.76%)	0.31	29 (52.73)	27 (54.0)	1.0	0	0	1.0
SWAP		Mean=18.1		Mean=16.3	Mean=17.4					Mean=17.7	Mean=17.5		Mean=19.3	Mean=17.4	
	Mean=13.0	7;		8;	2;		Mean=16.5	Mean=16.5		6;	6;		8;	3;	
	; SD=10.20;	SD=10.36;		SD=9.92;	SD=8.21;		8; SD=8.80;	9; SD=8.12;		SD=10.44;	SD=7.90;		SD=11.54;	SD=8.04;	
	N=8	N=12	0.33	N=42	N=40	0.6	N=73	N=79	0.48	N=55	N=50	0.91	N=26	N=28	0.48



#### Table 4 Mean Patient-Reported Outcomes Disease Duration, PHQ-8, and PAM Levels at 16-week follow-up

PRC	MIS-29
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Physical	Mean=-	Mean=-		Mean=0.5	Mean=0.1		Mean=0.	Mean=0.		Mean=0.	Mean=0.		Mean=0.3		
Function	1.53;	0.72;	0.81	6;	2;		04;	72;		05;	80;		3;	Mean=0.94	
	SD=3.89;	SD=8.73;	0.81	SD=5.74;	SD=5.64;		SD=5.44;	SD=4.72;		SD=3.66;	SD=5.05;		SD=2.71;	; SD=4.82;	
(	N=8	N=9		N=42	N=40	0.73	N=68	N=74	0.43	N=55	N=50	0.39	N=26	N=28	0.57
Social Role	Mean=4.9	Mean=-		Mean=7.2	Mean=2.6		Mean=6.	Mean=5.		Mean=-	Mean=-		Mean=-	Mean=-	
5; SD=	5;	0.74;	0.52	0;	6;		44;	13;		3.37;	2.03;		10.38;	4.25;	
	SD=18.94	SD=15.97		SD=16.12;	SD=15.27;		SD=15.9	SD=15.4		SD=17.3	SD=14.9		SD=15.97;	SD=17.97;	
	; N=8	; N=9		N=42	N=40	0.19	1; N=68	2; N=74	0.62	1; N=55	6; N=50	0.67	N=26	N=28	0.19
Anxiety	Mean=0.0	Mean=-	0.91	Mean=0.2	Mean=-		Mean=-	Mean=-		Mean=0.	Mean=-		Mean=0.4		
	3;	0.52;		4;	2.23;		0.35;	0.46;		80;	1.46;		4;	Mean=-3.0;	
	SD=8.85;	SD=9.77;		SD=6.89;	SD=8.40;		SD=6.03;	SD=7.72;		SD=7.91;	SD=7.58;		SD=9.46;	SD=6.35;	
	N=8	N=9		N=42	N=40	0.15	N=68	N=74	0.93	N=55	N=50	0.14	N=26	N=28	0.13
Depression	Mean=2.3	Mean=-		Mean=1.1	Mean=-		Mean=0.	Mean=0.		Mean=-	Mean=-		Mean=-	Mean=-	
	-0;	1.11;	0.44	7;	0.60;		75;	77;		0.74;	1.45;		1.42;	2.44;	
	SD=7.69;	SD=9.85;		SD=6.32;	SD=6.68;		SD=6.09;	SD=7.30;		SD=6.74;	SD=5.68;		SD=7.30;	SD=6.04;	
	N=8	N=9		N=42	N=40	0.22	N=68	N=74	0.99	N=55	N=50	0.56	N=26	N=28	0.58
Fatigue	Mean=-	Mean=-		Mean=0.4	Mean=-		Mean=0.	Mean=0.		Mean=-	Mean=0.		Mean=0.3	Mean=-	
	3.06;	1.13;	0.67	6;	1.82;		18;	30;		0.24;	06;		8;	0.22;	
r	SD=9.81;	SD=8.26;	0.07	SD=7.33;	SD=5.90;		SD=7.43;	SD=6.61;		SD=6.25;	SD=8.04;		SD=6.74;	SD=5.17;	
-	N=8	N=9		N=42	N=40	0.12	N=68	N=74	0.92	N=55	N=50	0.84	N=26	N=28	0.72
Pain	Mean=-	Mean=-		Mean=-	Mean=-		Mean=-	Mean=-		Mean=-	Mean=-		Mean=-		
nterference	0.33;	0.81;	0.86	0.51;	0.24;		1.05;	1.05;		0.16;	0.43;		1.65;	Mean=0.08	
	SD=6.07;	SD=4.56;	0.80	SD=7.52;	SD=6.38;		SD=7.34;	SD=7.04;		SD=6.48;	SD=6.86;		SD=6.34;	; SD=6.15;	
- 7	N=8	N=9		N=42	N=40	0.86	N=68	N=74	1.0	N=55	N=50	0.84	N=26	N=28	0.32
VAS Pain	Mean=-	Maar 0		Mean=0.1	Mean=-		Mean=0.	Mean=-		Mean=0.	Mean=-		Mean=-		
Intensity	0.13;	Mean=0; SD=1.32;	0.84	2;	0.25;		12;	0.16;		10;	0.22;		0.04;	Mean=0.07	
	SD=1.13;	SD=1.32; 0.84 N=9	0.64	SD=1.77;	SD=1.79;		SD=1.86;	SD=1.94;		SD=1.69;	SD=1.53;		SD=1.43;	; SD=1.12;	
	N=8	11-2		N=42	N=40	0.35	N=68	N=74	0.38	N=55	N=50	0.30	N=26	N=28	0.76
Sleep	Mean=-	Mean=-													
Disturbance	4.29;	2.18;	0.55	Mean=-	Mean=-		Mean=-	Mean=3.		Mean=2.	Mean=-		Mean=-	Mean=-	
	SD=7.23;	SD=7.05;		3.70;	2.36;	0.32	2.96;	48;	0.64	94;	3.28;	0.78	2.66;	4.26;	0.38

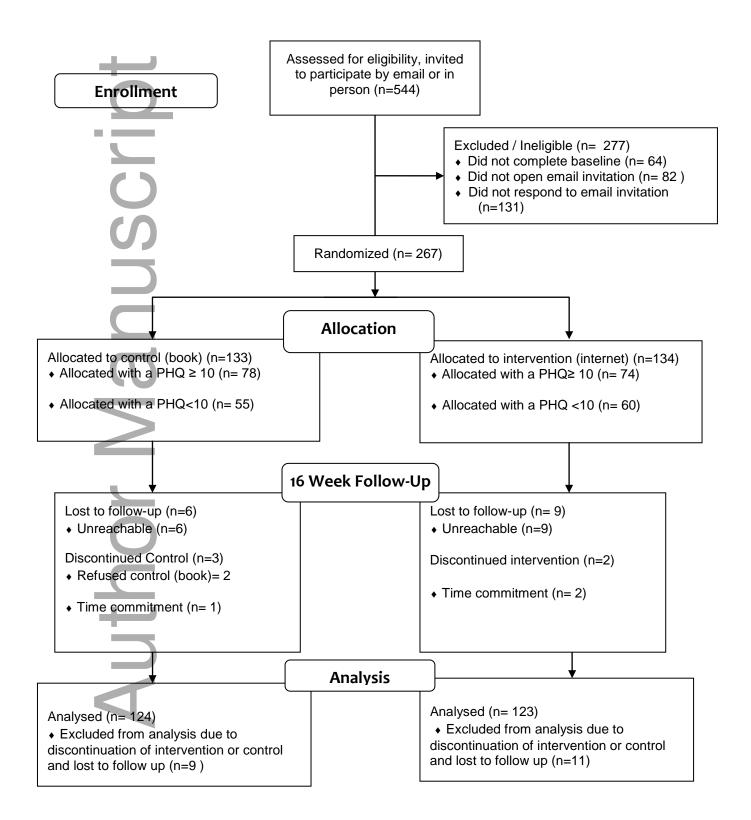
	N=8	N=9		SD=6.47;	SD=5.78;		SD=6.28;	SD=6.75;		SD=6.20;	SD=6.60;		SD=5.74;	SD=7.46;	
				N=42	N-40		N=68	N=74		N=55	N=50		N=26	N=28	
PHQ- 8	Mean=-	Mean=0.3		Mean=-	Mean=-		Mean=0.	Mean=0.		Mean=-	Mean=-		Mean=-	Mean=-	
	3.63;	3;	0.34	2.19;	1.33;		85;	84;		3.71;	4.40;		1.08;	1.68;	
	SD=8.33;	SD=8.22;	0.54	SD=5.77;	SD=5.01;		SD=3.39;	SD=3.98;		SD=5.57;	SD=4.72;		SD=4.94;	SD=4.74;	
	N=8	N=9		N=42	N=40	0.47	N=68	N=74	0.98	N=55	N=50	0.49	N=26	N=28	0.65
EQ-5D															
Mobility		Mean=0.2		Mean=-	Mean=0.0		Mean=-	Mean=0.		Mean=0.	Mean=-		Mean=-	Mean=-	
	Mean=0;	2;	0.40	0.05;	8;		0.07;	03;		09;	0.02;		0.08;	0.04;	
	SD=0.53; N=8	SD=0.44;	0.40	SD=0.54;	SD=0.42;		SD=0.43;	SD=0.50;		SD=0.52;	SD=0.43;		SD=0.39;	SD=0.33;	
	IN=0	N=9		N=42	N=40	0.26	N=68	N=74	0.21	N=55	N=50	0.23	N=26	N=28	0.68
Self-Care				Mean=-	Mean=-		Mean=0.	Mean=0.		Mean=0.	Mean=-			Mean=-	
	Mean=0;	Mean=0;	NT 4	0.05;	0.05;		01;	01;		07;	0.08;		Mean=0;	0.04;	
	SD=0; N=8	SD=0; N=9	NA	SD=0.44;	SD=0.45;		SD=0.37;	SD=0.39;		SD=0.47;	SD=0.34;		SD=0.49;	SD=0.43;	
	IN=0	N-9		N=42	N=40	0.79	N=68	N=74	0.99	N=55	N=50	0.02	N=26	N=28	0.52
Usual	U)	Mean=0.1			Mean=-		Mean=-	Mean=-		Mean=0.	Mean=0.		Mean=0.0		
Activities	Mean=0;	1;	0.00	Mean=0;	0.05;		0.03;	0.04;		05;	02;		8;	Mean=0;	
	SD=0.53;	SD=0.33;	0.66	SD=0.44;	SD=0.45;		SD=0.52;	SD=0.35;		SD=0.40;	SD=0.43;		SD=0.48;	SD=0.27;	
	N=8	N=9		N=42	N=40	0.61	N=68	N=74	0.94	N=55	N=50	0.68	N=26	N=28	0.64
Pain	Mean=0.1			Mean=0.0			Mean=0.	Mean=-			Mean=-		Mean=0.0	Mean=-	
Discomfort	3;	Mean=0;	0.61	2;	Mean=0;		06;	0.05;		Mean=0;	0.08;		4;	0.04;	
	SD=0.35;	SD=0.5; N=9	0.61	SD=0.47;	SD=0.39;		SD=0.45;	SD=0.43;		SD=0.43;	SD=0.44;		SD=0.34;	SD=0.51;	
	N=8	N-9		N=42	N=40	0.8	N=68	N=74	0.13	N=55	N=50	0.35	N=26	N=28	0.54
Anxiety	Mean=-	Mean=-		Mean=0.0	Mean=-		Mean=-	Mean=-		Mean=0.	Mean=-		Mean=0.0	Mean=-	
	0.13;	0.22;	0.00	5;	0.08;		0.01;	0.05;		07;	0.04;		4;	0.14;	
	SD=0.35;	SD=0.44;	0.66	SD=0.49;	SD=0.53;		SD=0.44;	SD=0.49;		SD=0.50;	SD=0.53;		SD=0.34;	SD=0.65;	
	N=8	N=9		N=42	N=40	0.28	N=68	N=74	0.61	N=55	N=50	0.18	N=26	N=28	0.09
VAS	Mean=3.8	Mean=-		Mean=-	Mean=-		Mean=0.	Mean=-		Mean=0.	Mean=5.		Mean=2.0		
	8;	1.67;	0.74	1.24;	0.08;		59;	1.11;		09;	10;		;	Mean=0.29	
	SD=12.57	SD=15.26		SD=15.28;	SD=15.54;		SD=15.2	SD=14.9		SD=17.8	SD=18.2		SD=16.76;	; SD=15.25;	
	; N=8	; N=9		N=42	N=40	0.73	7; N=68	5; N=74	0.51	2; N=55	5; N=50	0.16	N=26	N=28	0.70

EQ-5D Index	Mean=0.0	Mean=0.0		Mean=0.0	Mean=0.0		Mean=-	Mean=0.		Mean=-	Mean=0.		Mean=-		
	3;	2;	1.0	1;	09;		0.003;	01;		0.002;	03;		0.007;	Mean=0.03	
	SD=0.13;	SD=0.17;		SD=0.15;	SD=0.15;		SD=0.11;	SD=0.13;		SD=0.16;	SD=0.17;		SD=0.15;	; SD=0.21;	
	N=8	N=9		N=42	N=40	0.66	N=68	N=74	0.22	N=55	N=50	0.10	N=26	N=28	0.35
Patient Activation Measure (PAM)															
Mean PAM	Mean=0.7	Mean=4.5		Mean=31.	Mean=28.		Mean=1.	Mean=1.		Mean=2	Mean=2		Mean=23.	Mean=26.0	
Raw Score	5;	6;	0.19	13;	70;		25;	23;		5.07;	6.16;		76;	1;	
	SD=2.66;	SD=7.55;		SD=14.33;	SD=13.52;		SD=4.76;	SD=5.37;		SD=15.1	SD=15.6		SD=15.69;	SD=17.41;	
	N=8	N=9		N=42	N=40	0.43	N=68	N=74	0.98	7; N=55	1; N=50	0.72	N=26	N=28	0.61
Mean PAM	Mean=3.3	Mean=11.		Mean=2.1	Mean=6.1		Mean=4.	Mean=3.		Mean=0.	Mean=2.		Mean=12.	Mean=15.2	
Activation	0;	81;	0.33	8;	3;		01;	64;		44;	10;		58;	4;	
Score	SD=7.86;	SD=23.54	0.55	SD=12.09;	SD=14.29;		SD=14.6	SD=16.5		SD=15.1	SD=15.1		SD=15.21;	SD=17.29;	
	N=8	; N=9		N=42	N=40	0.18	5; N=68	0; N=74	0.89	8; N=55	4; N=50	0.58	N=26	N=28	0.55
SWAP	Mean=1.0	Mean=-		Mean=-	Mean=-		Mean=-	Mean=-		Mean=-	Mean=0.		Mean=0.7		
		6.0;	0.11	2.24;	2.50;		1.22;	0.66;		0.33;	20;		3;	Mean=1.82	
	SD=7.80;	SD=9.25;		SD=9.87;	SD=10.13;		SD=10.6	SD=9.25;		SD=10.5	SD=10.0		SD=13.96;	; SD=8.81;	
	N=8	N=9		N=42	N=40	0.91	4; N=68	N=74	0.74	7; N=55	8; N=50	0.79	N=26	N=28	0.74

Author N

# **\_\_\_** Author Manuscrip





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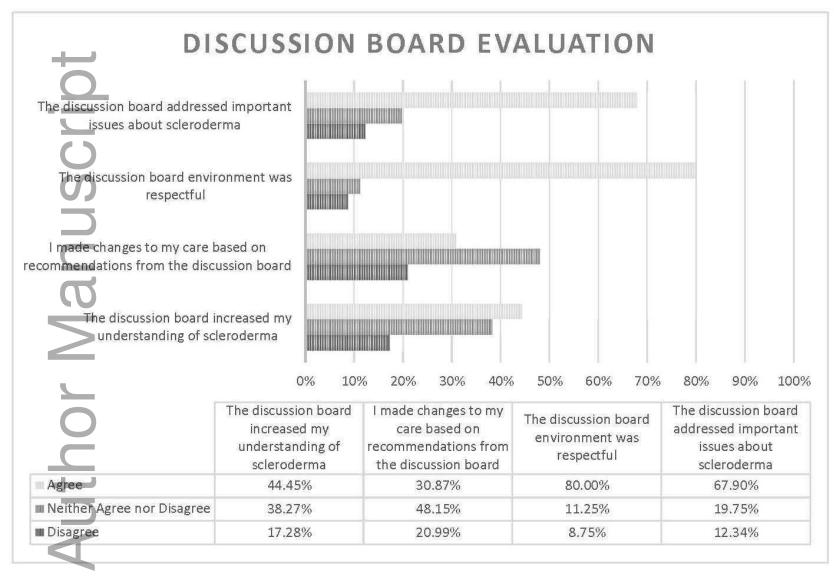


Figure 2. Discussion Board Evaluation. This figure provides an illustration of the responses received by internet participants after completion of the 16-week RCT