Arthritis Care & Research
Vol. 71, No. 3, March 2019, pp 435–447
DOI 10.1002/acr.23595

AMERICAN COLLEGE OF RHEUMATOLOGY
EDUCATION • TREATMENT • RESEARCH

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

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Objective. In a pilot study, our group showed that an internet-based self-management program improves self-efficacy in systemic sclerosis (SSc). The objective of the current study was to compare an internet-based self-management program to a patient-focused educational book developed to assess measures of self-efficacy and other patient-reported outcomes in patients with SSc.

Methods. We conducted a 16-week randomized, controlled trial.

Results. Of the 267 participants who completed baseline questionnaires and were randomized to the intervention (internet: www.selfmanagescleroderma.com) or control (book) group, 123 participants (93%) in the internet group and 124 participants (94%) in the control group completed the 16-week randomized controlled trial (RCT). The mean ± SD age of all participants was 53.7 ± 11.7 years, 91% were women, 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 (Patient-Reported Outcomes Measurement Information System Self-Efficacy for Managing Symptoms: mean change of 0.35 in the internet group versus 0.94 in the control group; $P = 0.47$) and secondary outcome measures, except the EuroQol 5-domain instrument visual analog scale score ($P = 0.05$). 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 about the content and presentation of the self-management website.

INTRODUCTION

Systemic sclerosis (SSc; scleroderma) 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 is characterized by disfigurement, hand contractures, fatigue, sleep disorders, low self-esteem, pain, and severe Raynaud's phenomenon, all of which are associated with significant functional and work disability and a decrement in quality of life. In addition, loss of productivity per person with the disease in the US is estimated to be $10,764 per year (3).

Clinicaltrials.gov identifier: NCT02494401.

The statements presented in this article are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute, its Board of Governors, or its Methodology Committee.

Supported by a Patient-Centered Outcomes Research Institute Award (CER-1310-08323). Dr. Khanna's work was supported by the NIH/National Institute of Arthritis and Musculoskeletal and Skin Diseases (K24-AR-063129).

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Dr. Khanna has received consulting fees from Actelion, AstraZeneca, Bayer, Boehringer Ingelheim, Chemomab, Corbus, Covis, Cytori, Eicos (with ownership interest), EMD Serono, Genentech/Roche, Gilead, GlaxoSmithKline, Sanofi-Aventis, and UCB (less than $10,000 each), and has received grants from Bayer, Bristol-Myers Squibb, Boehringer Ingelheim, Genentech/Roche, Pfizer, and Sanofi-Aventis.

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Submitted for publication November 6, 2017; accepted in revised form May 1, 2018.

SIGNIFICANCE & INNOVATIONS

- Systemic sclerosis is a rare disease and many patients do not have access to educational programs.
- We performed a randomized, controlled trial comparing an internet-based self-management program to a patient-focused educational book in measures of self-efficacy and other patient-reported outcomes.
- The self-management website was not superior to a patient-focused educational book in improving self-efficacy and other measures.
- The participants were enthusiastic about the content and presentation of the self-management website and endorsed it for dissemination.

Because SSc is a rare disease, many patients with SSc do not have access to educational 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 patients 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 the course of 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 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 pharmacologic treatments have emerged (1). Thus, the self-management program was revised and updated with input from patient partners and stakeholders (the Scleroderma Foundation and the Scleroderma Research Foundation) (6). In this article, we report our findings in a randomized controlled trial (RCT) conducted to evaluate the efficacy of the internet-based self-management program versus the patient book developed for patients with SSc for improving self-efficacy and other patient-reported outcome measures. We hypothesized that the internet-based self-management program was superior to the book in primary (self-efficacy) and secondary patient-reported outcome measures.

PATIENTS AND METHODS

Participants. Patients 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 the Scleroderma Research Foundation (self-identified SSc). Inclusion criteria were being residents of the US, having a diagnosis of SSc, being age ≥18 years, having basic computer literacy and access to a computer with internet and email capabilities, having communication skills in English, and being willing 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, the University of Michigan, and the Medical University of South Carolina.

Outcome measures. Demographic information, including age, sex, 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. 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 in attaining self-management skills in chronic diseases (8,9). To measure self-efficacy (10), we administered the PROMIS Self-Efficacy for Managing Chronic Conditions instrument, which comprises 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 units and the SD was 10 units, and results were scored by uploading the data at http://www.healthmeasures.net/explore-measurement-systems/promis. We used the domain for managing symptoms as the primary outcome measure.

The PROMIS-29 Profile version 2.0 measure contains 29 items, 1 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 the method described at http://www.healthmeasures.net/explore-measurement-systems/promis. The Patient Health Questionnaire 8 (PHQ-8) is an 8-item questionnaire that is commonly used to measure depressive symptoms (12). A score of ≥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 score that can range from 13.0 to 52.0. The summed score

is finally transformed into a 0–100 scale, with higher scores indicating more confidence and knowledge in patients managing their condition. PAM scores were categorized into 4 levels: level 1, the individual is disengaged and overwhelmed; level 2, the individual is aware but struggling; level 3, the individual is taking action; and level 4, the individual is maintaining behavior (https://www.insigniahealth.com/products/pam-survey). The PAM has been extensively used in different self-management courses (14).

The EuroQol 5-domain instrument (EQ-5D) and quality-adjusted life years (QALYs) provide a generic health-related quality of life assessment. The EQ-5D incorporates patient-reported outcomes across 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 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 data from the pilot study, we expected that the effect size 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 (effect size = 0.10). Using a significance level of 0.05, we estimated that recruiting 100 participants in each group would yield an 80% power for detecting this difference between the intervention group 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 platform. Once signed consents were obtained, participants were invited to complete the baseline questionnaire. Participants who completed the consent form 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 (<10 or ≥ 10) to ensure that subjects with depressive symptoms were equally distributed in the 2 groups. Stratification based on the PHQ-8 score was used 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 process 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 be accessed only via a secured website, with 1 module focus made available per week. The 15 modules included a 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. Two investigators (SLN and JLP) posted weekly questions regarding the modules on the discussion board and moderated the online discussion as necessary (see Supplementary Appendix A, available on the *Arthritis Care & Research* web site at http://onlinelibrary.wiley.com/doi/10.1002/acr.23595/abstract). 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 and were given 16 weeks to read it. 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 versus standard care). Group differences for these characteristics were tested using either *t*-tests, Wilcoxon's rank-sum test for dependent samples, a proportion test, or chi-square tests, depending on the type of data (continuous versus categorical, or normally distributed versus not normally distributed).

To compare group differences between the intervention and control groups post-intervention, 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 percentage of patients were

categorized as having 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 2 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 by using Wilcoxon's tests if a normal distribution did not seem appropriate. For categorical variables, we assessed whether there was a significant difference between the two groups in the joint distribution of the categorical variable at baseline and follow-up in the 2 groups using Fisher's exact test 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 the internet or control groups. Of these 267 participants who completed baseline questionnaires and were randomized to the intervention (internet) or control (book) group (Figure 1), 123 participants (93%) in the internet and 124 participants (94%) in the control groups completed the 16-week RCT. The 2 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 women, 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% classifying themselves as having limited/sine and 43.1% as diffuse SSc.

Regardless of the group, participants had similar mean scores on patient-reported outcome measures (PROs), except

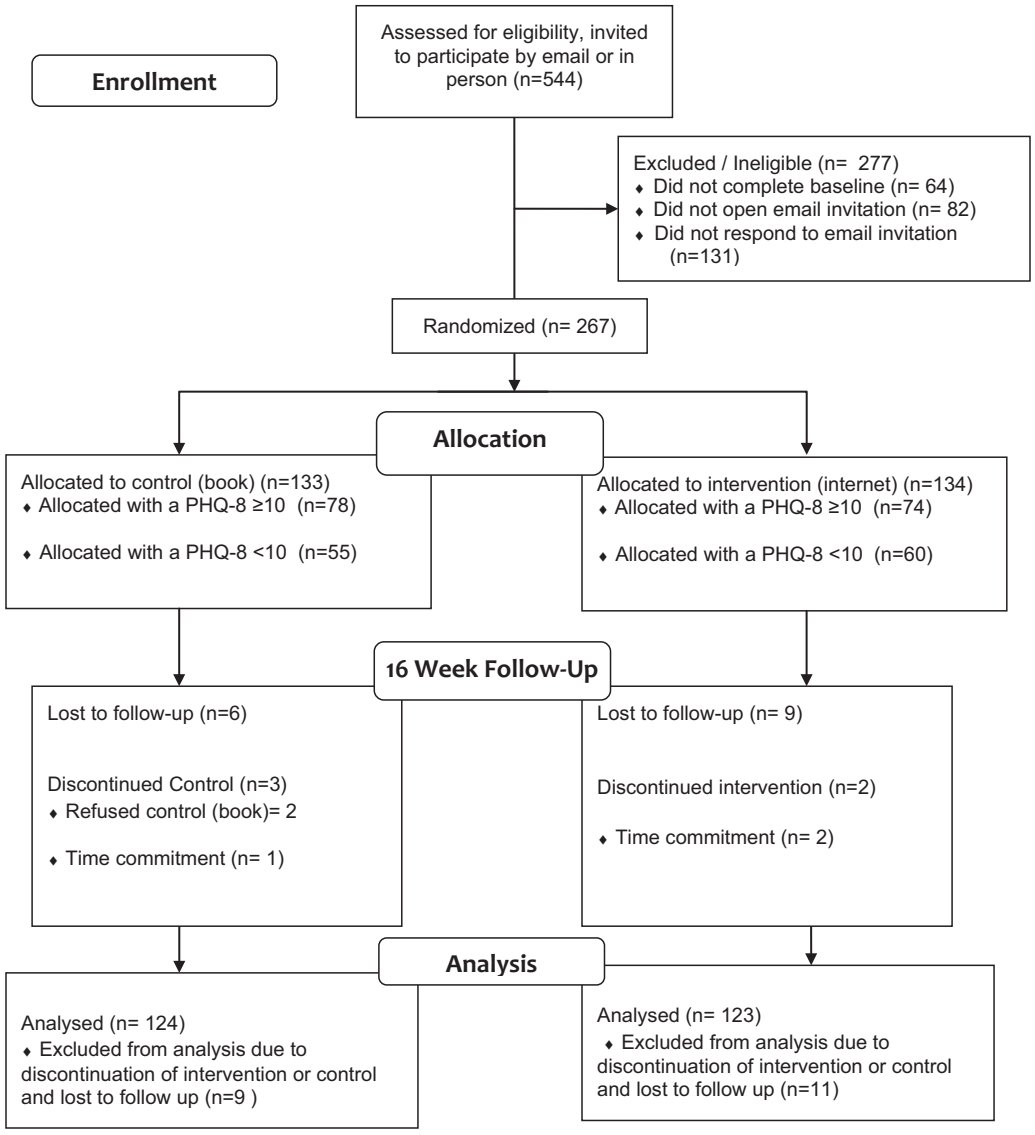


Figure 1. Flow diagram for participants in the trial, using the Consolidated Standards of Reporting Trials. PHQ-8 = Patient Health Questionnaire.

Table 1. Baseline characteristics of the 267 participants in the randomized clinical trial*

Characteristic	Values	Intervention (n = 134)	Control (n = 133)	*P*
Age, mean ± SD years	53.7 ± 11.7	54.3 ± 10.1	52.9 ± 13.1	0.33
Women	91 (243)	91.8 (123)	90.2 (120)	0.82
Race				
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/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				
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 (years)				
High school (9–12)	20.6 (55)	20.1 (27)	21.1 (28)	0.98
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
Postgraduate school (≥23)	4.1 (11)	3.7 (5)	4.5 (6)	0.99
Marital status				
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				
Working full time (≥20 hours/week)	35.6 (95)	35.8 (48)	35.3 (47)	1
Working part time (<20 hours/week)	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 subtype				
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 years				
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				
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

(Continues)

Table 1. *(Cont'd)*

Characteristic	Values	Intervention (n = 134)	Control (n = 133)	*P*
Fair	37.4 (100)	34.3 (46)	40.6 (54)	0.35
Poor	6.4 (17)	7.5 (10)	5.3 (7)	0.63
US geographic region				
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

* Values are the number (%) unless indicated otherwise.

for the EQ-5D visual analog scale, 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 for Managing Medications and Treatment) to being 1.00 SD below the mean score in the US population (PROMIS-29 physical function scale). The mean ± SD PHQ-8 score was 8.67 ± 5.18, and 43.1% participants had depressed mood. Regarding the PAM scores, 18.7% and 59.6% of participants had PAM level 3 and PAM level 4, respectively.

Table 2 shows the mean change scores for the 2 groups between baseline and post-intervention at 16 weeks for all variables. There were no statistically significant differences between the 2 groups for the primary outcome measure (PROMIS Self-Efficacy for Managing Symptoms: mean change of 0.35 in the internet group versus 0.94 in the 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 changed from baseline to follow-up.

Because 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-8 score <10, PHQ-8 score ≥10, and PAM levels 1 and 2 (Table 3). Again, there were no differences between the 2 groups, except for PROMIS Self-Efficacy for 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-8 scores ≥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 1 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 participants (74.6%) completed a course evaluation, in which they were asked to rate each module as helpful, slightly helpful, not helpful at all, or they did not review the module (see Supplementary Figure 1, available on the *Arthritis Care & Research* web site at http://onlinelibrary.wiley.com/doi/10.1002/acr.23595/abstract). An average of 75.4% of participants rated the modules as being helpful. Key modules (those that had more than 60 hours of time spent) 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 that 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 patients with scleroderma. When asked about their impression of the self-management course, an overwhelming 93.0% of participants 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. In summary, 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.

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 compared to using the book, participants from the intervention showed overwhelming support and enthusiasm for the content and presentation on the website (see Supplementary Figure 1, available on the *Arthritis Care & Research* web site at http://onlinelibrary.wiley.com/doi/10.1002/acr.23595/abstract).

Based on input from the patient and stakeholder partners, we stratified the randomization with respect to PHQ-8 scores as <10 versus ≥10, because we hypothesized that participants who have depressed mood may exhibit poor coping skills. Although participants with PHQ-8 scores of ≥10 had lower scores on self-efficacy and PROMIS-29 scores (Table 3), there was no benefit in the inter-

Table 2. Mean patient-reported outcome measures at baseline, 16 weeks, and changes score over 16 weeks*

Scales	Baseline			16 weeks			Change		
	Internet (n = 134)	Control (n = 133)	*P*	Internet (n = 123)	Control (n = 124)	*P*	Internet (n = 123)	Control (n = 124)	*P*
PROMIS self-efficacy									
Managing emotions	46.78 ± 9.29†	46.34 ± 8.75	0.69	46.6 ± 9.20	47.20 ± 9.33	0.62	0.09 ± 6.28‡	0.73 ± 5.34	0.29
Managing symptoms	47.41 ± 9.15	47.58 ± 7.81	0.87	47.53 ± 8.50	48.61 ± 8.70	0.32	0.35 ± 6.12	0.94 ± 6.79	0.47
Managing daily activities	44.83 ± 7.60	44.71 ± 6.77	0.89	45.18 ± 7.84	45.37 ± 7.70	0.85	0.17 ± 5.11	0.79 ± 4.52	0.32
Managing social interactions	46.57 ± 9.74	46.66 ± 8.96	0.93	46.91 ± 9.63	47.43 ± 9.50	0.67	0.43 ± 6.94	0.99 ± 7.42	0.54
Managing medications and treatment	49.15 ± 9.06	50.3 ± 8.29	0.28	49.0 ± 8.99	50.85 ± 9.28	0.05	−0.54 ± 7.59	0.70± 6.29	0.16
PROMIS-29									
Physical function	40.63 ± 6.95	40.17 ± 6.15	0.59	40.81 ± 8.14	40.86 ± 7.30	0.96	0.05 ± 5.71	0.75 ± 4.83	0.25
Social role	43.74 ± 8.63	44.39 ± 7.68	0.51	45.82 ± 9.46	46.68 ± 8.86	0.46	2.05 ± 17.19	2.24 ± =15.58	0.93
Anxiety	53.85 ± 9.72	54.11 ± 10.31	0.83	54.14 ± 10.25	53.06 ± 10.11	0.41	0.16 ± 6.93	−0.86 ± 7.64	0.27
Depression	51.04 ± 10.03	51.59 ± 9.69	0.64	51.29 ± 9.53	51.22 ± 9.70§	0.96	0.08 ± 6.40	−0.13 ± 6.76	0.8
Fatigue	58.47 ± 10.52	58.91 ± 10.31	0.73	58.06 ± 10.59	59.24 ± 10.96§	0.67	−0.005 ± 6.90	0.20 ± 7.19	0.82
Pain interference	57.99 ± 9.37	57.92 ± 9.22	0.95	57.09 ± 9.20	57.37 ± 9.50	1	−0.65 ± 6.96	−0.80 ± 6.95	0.87
VAS pain intensity	4.08 ± 2.21	4.25 ± 2.26	0.65	4.13 ± 2.29	4.14 ± 2.26	0.98	0.11 ± 1.78	−0.19 ± 1.78	0.19
Sleep disturbance	55.22 ± 6.96	56.18 ± 7.84	0.29	52.08 ± 7.28	52.80 ± 7.91	0.46	−2.95 ± 6.22	−3.40 ± 6.62	0.58
PHQ-8	8.61 ± 5.39	8.72 ± 4.98	0.87	7.44 ± 5.56	7.40 ± 5.65	0.96	−1.19 ± 5.02	−1.27 ± 4.99	0.89
EQ-5D									
Mobility	1.53 ± 0.52	1.61 ± 0.49	0.18	1.54 ± 0.50	1.63 ± 0.49	0.14	0.0 ± 0.48	0.01 ± 0.47	0.89
Self-care	1.28 ± 0.48	1.35 ± 0.49	0.19	1.33 ± 0.51	1.32 ± 0.49	0.93	0.04 ± 0.41	−0.02 ± 0.37	0.13
Usual activities	1.78 ± 0.50	1.79 ± 0.43	0.82	1.78 ± 0.54	1.77 ± 0.46	0.94	0.01 ± 0.47	−0.02 ± 0.38	0.76
Pain discomfort	1.93 ± 0.48	2.02 ± 0.43	0.11	1.93 ± 0.43	1.96 ± 0.45	0.57	0.03 ± 0.44	−0.06 ± 0.44	0.08
Anxiety	1.56 ± 0.61	1.63 ± 0.62	0.34	1.57 ± 0.57	1.57 ± 0.63	0.87	0.02 ± 0.47	−0.05 ± 0.51	0.19
EQ-5D VAS	67.47 ± 18.01	63.72 ± 17.33	0.05	68.28 ± 18.61	64.92 ± 19.13	0.14	0.37 ± 16.39	1.40 ± 16.57	0.62
EQ-5D index	0.71 ± 0.18	0.69 ± 0.16	0.08	0.72 ± 0.17	0.71 ± 0.17	0.69	−0.002 ± 0.14	0.02 ± 0.14	0.05
SWAP	17.1 ± 9.53	16.81 ± 8.13	0.96	16.47 ± 9.47	16.76 ± 9.08	0.81	−0.82 ± 10.58	−0.31 ± 9.56	0.69
PAM level, no. (%)									
Level 1	14 (10.45)	14 (10.53)	1	10 (8.13)	12 (9.68)	0.82	NA	NA	
Level 2	15 (11.19)	15 (11.28)	1	13 (10.57)	13 (10.48)	1	NA	NA	
Level 3	23 (17.16)	27 (20.30)	0.53	26 (21.14)	22 (17.74)	0.52	NA	NA	
Level 4	82 (61.19)	77 (57.89)	0.62	74 (60.16)	77 (62.10)	0.79	NA	NA	

* Values are the mean ± SD unless indicated otherwise. PROMIS = Patient-Reported Outcomes Measurement Information System; VAS = visual analog scale; PHQ-8 = Patient Health Questionnaire 8; EQ-5D = EuroQol 5-domain instrument; SWAP = Brief Satisfaction with Appearance Scale; PAM = Patient Activation Measure; NA = not applicable.
† N = 133.
‡ N = 122.
§ N = 123.

Table 3. Mean patient-reported outcome measures disease duration, PHQ-8, and PAM levels at baseline*

	Disease <2 years			Disease <5 years			PHQ-8 <10			PHQ-8 ≥10			PAM level 1–2		
Scales	Treatment baseline (n = 8)	Control baseline (n = 12)	*P*	Treatment baseline (n = 42)	Control baseline (n = 40)	*P*	Treatment baseline (n = 73)	Control baseline (n = 79)	*P*	Treatment baseline (n = 55)	Control baseline (n = 50)	*P*	Treatment baseline (n = 26)	Control baseline (n = 28)	*P*
PROMIS self efficacy															
Managing emotions	46.80 ± 9.25	44.06 ± 10.24	0.54	49.26 ± 10.33†	46.14 ± 8.37	0.14	49.47 ± 8.29‡	47.59 ± 8.58	0.17	43.45 ± 9.76	44.33 ± 9.00	0.63	39.55 ± 7.31	40.53 ± 6.74	0.61
Managing symptoms	49.96 ± 10.72	47.51 ± 5.51	0.56	50.32 ± 9.25	47.15 ± 7.05	0.08	49.81 ± 8.44	48.04 ± 7.89	0.18	44.28 ± 9.05	46.86 ± 7.97	0.12	39.06 ± 6.09	42.25 ± 6.08	0.06
Managing daily activities	46.11 ± 7.84	43.16 ± 4.48	0.36	46.53 ± 7.77	44.52 ± 6.04	0.19	46.59 ± 7.93	45.87 ± 7.37	0.56	42.77 ± 6.40	42.79 ± 5.38	0.99	40.05 ± 5.74	42.22 ± 6.41	0.20
Managing social interactions	47.31 ± 7.28	47.18 ± 8.54	0.97	49.10 ± 9.90	47.01 ± 8.32	0.3	49.33 ± 9.38	46.61 ± 9.22	0.07	43.13 ± 9.30	45.93 ± 8.34	0.11	38.76 ± 7.26	39.99 ± 5.33	0.48
Managing medications and treatment	53.62 ± 5.08	50.58 ± 7.48	0.29	50.23 ± 9.45	49.53 ± 8.41	0.72	50.92 ± 8.64	50.94 ± 7.97	0.99	47.07 ± 9.30	48.88 ± 8.76	0.31	42.01 ± 6.52	45.29 ± 8.50	0.12
PROMIS-29															
Physical function	43.79 ± 8.95	38.92 ± 5.06	0.19	43.26 ± 8.05	39.98 ± 5.96	0.04	42.04 ± 8.17	41.28 ± 6.28	0.52	38.95 ± 6.57	38.4 ± 5.64	0.65	36.18 ± 5.38	37.0 ± 6.43	0.61
Social role	41.56 ± 9.64	46.78 ± 6.53	0.21	41.40 ± 8.00	44.44 ± 8.22	0.09	41.52 ± 7.80	43.19 ± 7.28	0.18	46.51 ± 8.88	46.46 ± 8.03	0.98	50.63 ± 8.70	47.84 ± 9.68	0.27
Anxiety	56.18 ± 9.54	58.38 ± 9.10	0.61	52.86 ± 10.2	53.98 ± 9.14	0.6	50.53 ± 8.16	51.39 ± 8.86	0.53	57.93 ± 10.23	58.52 ± 11.17	0.78	59.72 ± 9.07	61.68 ± 9.03	0.43
Depression	52.34 ± 10.14	54.95 ± 11.60	0.60	49.87 ± 9.36	50.76 ± 10.21	0.68	47.76 ± 7.79	48.8 ± 8.01	0.42	55.14 ± 11.21	55.98 ± 10.73	0.69	58.88 ± 10.31	58.23 ± 7.87	0.8
Fatigue	57.89 ± 12.33	61.91 ± 9.46	0.45	54.82 ± 10.53	60.33 ± 8.81	0.01	55.22 ± 10.27	56.77 ± 9.51	0.34	62.11 ± 9.67	62.04 ± 10.74	0.97	63.21 ± 7.79	64.31 ± 9.06	0.63
Pain interference	59.69 ± 12.28	59.55 ± 7.92	0.98	55.62 ± 10.06	57.47 ± 9.33	0.39	55.85 ± 8.59	56.51 ± 9.34	0.65	60.55 ± 9.72	60.40 ± 8.62	0.93	62.41 ± 8.61	62.45 ± 8.65	1.0
VAS pain intensity	4.63 ± 2.72	4.83 ± 2.29	0.86	4.05 ± 2.12	4.35 ± 1.89	0.5	3.67 ± 2.08	3.91 ± 2.23	0.49	3.78 ± 1.93	4.1 ± 2.28	0.44	4.27 ± 1.61	4.21 ± 1.99	0.91
Sleep disturbance	56.21 ± 6.49	57.04 ± 8.33	0.81	54.53 ± 7.47	56.02 ± 8.41	0.4	53.63 ± 7.12	55.08 ± 7.51	0.22	56.95 ± 6.20	57.59 ± 7.90	0.65	58.09 ± 6.25	59.89 ± 6.56	0.31
PHQ-8	11.62 ± 3.62	10.42 ± 5.26	0.55	9.26 ± 5.43	8.80 ± 5.40	0.7	4.49 ± 2.74	5.35 ± 2.55	0.05	13.76 ± 3.23	13.62 ± 3.33	0.82	11.54 ± 6.33	11.57 ± 5.55	0.98

(Continues)

Table 3. *(Cont'd)*

Scales	Disease <2 years			Disease <5 years			PHQ-8 <10			PHQ-8 ≥10			PAM level 1–2		
	Treatment baseline (n = 8)	Control baseline (n = 12)	*P*	Treatment baseline (n = 42)	Control baseline (n = 40)	*P*	Treatment baseline (n = 73)	Control baseline (n = 79)	*P*	Treatment baseline (n = 55)	Control baseline (n = 50)	*P*	Treatment baseline (n = 26)	Control baseline (n = 28)	*P*
EQ-5D															
Mobility	1.5 ± 0.53	1.42 ± 0.51	0.75	1.45 ± 0.50	1.45 ± 0.50	0.99	1.48 ± 0.50	1.54 ± 0.50	0.43	1.62 ± 0.53	1.72 ± 0.45	0.26	1.89 ± 0.33	1.75 ± 0.44	0.21
Self-care	1.38 ± 0.52	1.25 ± 0.45	0.59	1.31 ± 0.52	1.35 ± 0.48	0.59	1.22 ± 0.45	1.30 ± 0.49	0.23	1.36 ± 0.52	1.42 ± 0.50	0.49	1.65 ± 0.63	1.5 ± 0.51	0.41
Usual activities	1.75 ± 0.89	1.83 ± 0.39	0.63	1.76 ± 0.58	1.83 ± 0.45	0.5	1.75 ± 0.50	1.76 ± 0.43	0.86	1.82 ± 0.51	1.84 ± 0.42	0.76	2.0 ± 0.4	1.93 ± 0.38	0.51
Pain discomfort	1.88 ± 0.64	2.08 ± 0.51	0.44	1.79 ± 0.52	2 ± 0.39	0.04	1.88 ± 0.47	1.99 ± 0.38	0.10	1.96 ± 0.47	2.08 ± 0.49	0.22	2.08 ± 0.27	2.14 ± 0.45	0.49
Anxiety	1.75 ± 0.70	2 ± 0.60	0.40	1.52 ± 0.67	1.63 ± 0.59	0.33	1.43 ± 0.52	1.49 ± 0.55	0.45	1.71 ± 0.69	1.84 ± 0.68	0.31	1.89 ± 0.65	2.0 ± 0.61	0.50
EQ-5D VAS	62.0 ± 20.99	58.25 ± 21.83	0.91	70.88 ± 17.85	63.85 ± 18.67	0.09	71.6 ± 16.95	71.6 ± 15.63	0.10	62.89 ± 18.90	56.66 ± 18.06	0.09	57.31 ± 16.12	57.5 ± 18.88	0.97
EQ-5D index	0.68 ± 0.26	0.64 ± 0.18	0.51	0.74 ± 0.20	0.70 ± 0.14	0.09	0.75 ± 0.15	0.72 ± 0.13	0.06	0.67 ± 0.20	0.63 ± 0.19	0.30	0.59 ± 0.16	0.60 ± 0.19	0.83
PAM, mean scores															
Raw score	43.88 ± 4.85	40.92 ± 5.96	0.28	45.0 ± 5.22	41.58 ± 5.99	0.007	44.77 ± 5.16	43.72 ± 5.54	0.23	42.25 ± 6.75	42.50 ± 5.98	0.84	34.88 ± 3.15	34.82 ± 2.68	0.94
Activation score	69.89 ± 13.92	62.96 ± 17.14	0.28	73.95 ± 15.92	64.14 ± 16.57	0.008	73.21 ± 15.24	70.36 ± 15.70	0.26	66.88 ± 19.04	66.56 ± 16.70	0.93	46.07 ± 5.96	45.6 ± 4.91	0.76
PAM level, no. (%)															
1	0 (0)	2 (16.67)	0.49	2 (4.76)	8 (20)	0.05	3 (4.11)	7 (8.86)	0.33	10 (18.18)	7 (14.0)	0.61	12 (46.15)	14 (50.0)	0.79
2	2 (25.0)	2 (16.67)	1.0	4 (9.52)	5 (12.5)	0.73	8 (10.96)	6 (7.59)	0.58	6 (10.91)	8 (16.0)	0.57	14 (53.85)	14 (50.0)	0.79
3	1 (12.5)	4 (33.33)	0.6	6 (14.29)	10 (25.0)	0.27	11 (15.07)	18 (22.78)	0.30	10 (18.18)	8 (16.0)	0.8	0	0	1.0
4	5 (62.5)	4 (33.33)	0.36	30 (71.43)	17 (42.5)	0.01	51 (69.86)	8 (60.76)	0.31	29 (52.73)	27 (54.0)	1.0	0	0	1.0
SWAP	13.0 ± 10.20	18.17 ± 10.36	0.33	16.38 ± 9.92	17.42 ± 8.21	0.6	16.58 ± 8.80	16.59 ± 8.12	0.48	17.76 ± 10.44	17.56 ± 7.90	0.91	19.38 ± 11.54	17.43 ± 8.04	0.48

* Values are the mean ± SD unless indicated otherwise. PHQ-8 = 8-item Patient Health Questionnaire; PAM = Patient Activation Measure; PROMIS = Patient-Reported Outcomes Measurement Information System; VAS = visual analog scale; EQ-5D = EuroQol 5-domain instrument; SWAP = Brief Satisfaction with Appearance Scale.
† N = 41.
‡ N = 72.

Table 4. Mean patient-reported outcome measures disease duration, PHQ-8, and PAM levels at 16-week follow-up*

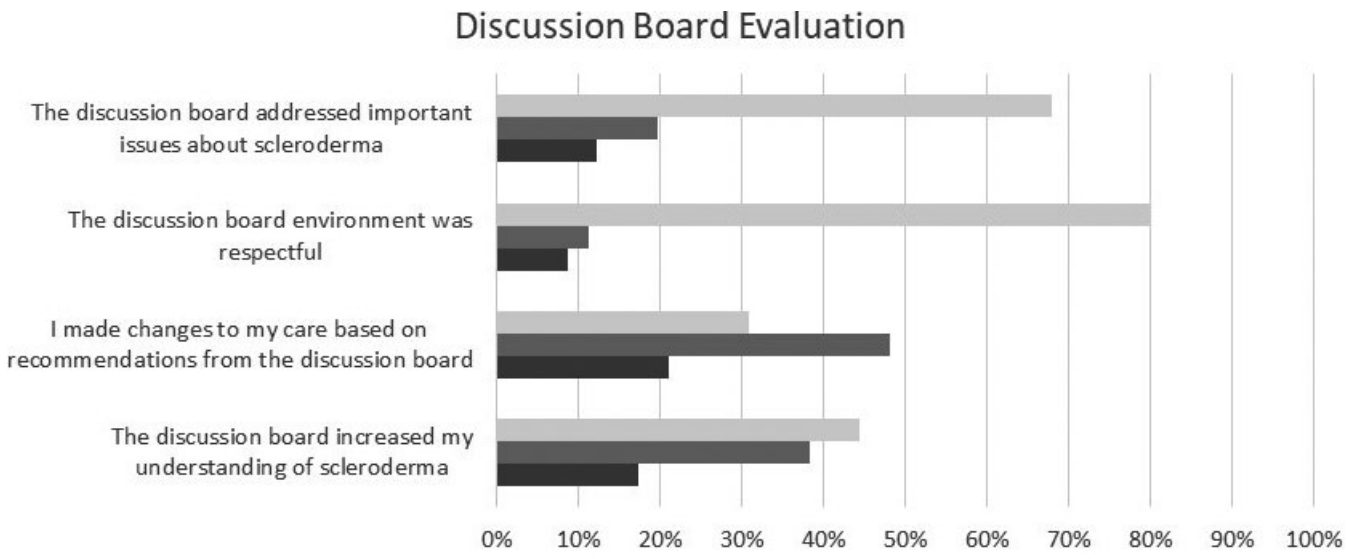
	Disease <2 years			Disease <5 years			PHQ-8 <10			PHQ-8 ≥10			PAM level 1–2		
Scales	Treatment change (n = 8)	Control change (n = 9)	*P*	Treatment change (n = 42)	Control change (n = 40)	*P*	Treatment change (n = 68)	Control change (n = 74)	*P*	Treatment change (n = 55)	Control change (n = 50)	*P*	Treatment change	Control change	*P*
PROMIS self-efficacy															
Managing emotions	−1.06 ± 7.04	0.11 ± 7.52	0.74	−1.51 ± 7.93†	0.93 ± 6.28	0.13	−0.24 ± 6.91‡	0.91 ± 6.06	0.30	0.10 ± 5.47	0.47 ± 5.80	0.76	1.37 ± 5.35	1.74 ± 5.27	0.80
Managing symptoms	−4.03 ± 6.92	0.38 ± 7.50	0.23	−1.28 ± 6.50	1.85 ± 5.98	0.03	0.15 ± 6.79	1.16 ± 6.93	0.39	0.59 ± 5.22	0.63 ± 6.65	0.97	2.79 ± 5.91	1.81 ± 7.45	0.59
Managing daily activities	−0.98 ± 2.62	1.96 ± 5.67	0.19	1.25 ± 6.27	0.35 ± 4.53	0.46	−0.01 ± 6.13	0.52 ± 4.63	0.57	0.4 ± 3.51	1.19 ± 4.37	0.31	0.48 ± 2.98	1.05 ± 4.04	0.55
Managing social interactions	−1.66 ± 11.19	0.97 ± 9.79	0.62	−0.20 ± 6.77	0.53 ± 6.94	0.63	−0.55 ± 7.53	0.76 ± 7.52	0.30	1.63 ± 5.98	1.33 ± 7.33	0.82	1.50 ± 8.65	1.85 ± 7.20	0.87
Managing medications and treatment	−2.15 ± 5.77	2.94 ± 7.42	0.13	0.54 ± 7.07	1.85 ± 6.90	0.40	−1.14 ± 6.84	0.86 ± 6.48	0.08	0.20 ± 8.44	0.47 ± 5.05	0.85	1.22 ± 6.91	−0.77 ± 5.53	0.25
PROMIS-29															
Physical function	−1.53 ± 3.89	−0.72 ± 8.73	0.81	0.56 ± 5.74	0.12 ± 5.64	0.73	0.04 ± 5.44	0.72 ± 4.72	0.43	0.05 ± 3.66	0.80 ± 5.05	0.39	0.33 ± 2.71	0.94 ± 4.82	0.57
Social role	4.95 ± 18.94	−0.74 ± 15.97	0.52	7.20 ± 16.12	2.66 ± 15.27	0.19	6.44 ± 15.91	5.13 ± 15.42	0.62	−3.37 ± 17.31	−2.03 ± 14.96	0.67	−10.38 ± 15.97	−4.25 ± 17.97	0.19
Anxiety	0.03 ± 8.85	−0.52 ± 9.77	0.91	0.24 ± 6.89	−2.23 ± 8.40	0.15	−0.35 ± 6.03	−0.46 ± 7.72	0.93	0.80 ± 7.91	−1.46 ± 7.58	0.14	0.44 ± 9.46	−3.0 ± 6.35	0.13
Depression	2.30 ± 7.69	−1.11 ± 9.85	0.44	1.17 ± 6.32	−0.60 ± 6.68	0.22	0.75 ± 6.09	0.77 ± 7.30	0.99	−0.74 ± 6.74	−1.45 ± 5.68	0.56	−1.42 ± 7.30	−2.44 ± 6.04	0.58
Fatigue	−3.06 ± 9.81	−1.13 ± 8.26	0.67	0.46 ± 7.33	−1.82 ± 5.90	0.12	0.18 ± 7.43	0.30 ± 6.61	0.92	−0.24 ± 6.25	0.06 ± 8.04	0.84	0.38 ± 6.74	−0.22 ± 5.17	0.72
Pain interference	−0.33 ± 6.07	−0.81 ± 4.56	0.86	−0.51 ± 7.52	−0.24 ± 6.38	0.86	−1.05 ± 7.34	−1.05 ± 7.04	1.0	−0.16 ± 6.48	−0.43 ± 6.86	0.84	−1.65 ± 6.34	0.08 ± 6.15	0.32
VAS pain intensity	−0.13 ± 1.13	0 ± 1.32	0.84	0.12 ± 1.77	−0.25 ± 1.79	0.35	0.12 ± 1.86	−0.16 ± 1.94	0.38	0.10 ± 1.69	−0.22 ± 1.53	0.30	−0.04 ± 1.43	0.07 ± 1.12	0.76
Sleep disturbance	−4.29 ± 7.23	−2.18 ± 7.05	0.55	−3.70 ± 6.47	−2.36 ± 5.78	0.32	−2.96 ± 6.28	3.48 ± 6.75	0.64	2.94 ± 6.20	−3.28 ± 6.60	0.78	−2.66 ± 5.74	−4.26 ± 7.46	0.38
PHQ-8	−3.63 ± 8.33	0.33 ± 8.22	0.34	−2.19 ± 5.77	−1.33 ± 5.01	0.47	0.85 ± 3.39	0.84 ± 3.98	0.98	−3.71 ± 5.57	−4.40 ± 4.72	0.49	−1.08 ± 4.94	−1.68 ± 4.74	0.65

(Continues)

Table 4. *(Cont'd)*

Scales	Disease <2 years			Disease <5 years			PHQ-8 <10			PHQ-8 ≥10			PAM level 1–2		
	Treatment change (n = 8)	Control change (n = 9)	*P*	Treatment change (n = 42)	Control change (n = 40)	*P*	Treatment change (n = 68)	Control change (n = 74)	*P*	Treatment change (n = 55)	Control change (n = 50)	*P*	Treatment change	Control change	*P*
EQ-5D															
Mobility	0 ± 0.53	0.22 ± 0.44	0.40	−0.05 ± 0.54	0.08 ± 0.42	0.26	−0.07 ± 0.43	0.03 ± 0.50	0.21	0.09 ± 0.52	−0.02 ± 0.43	0.23	−0.08 ± 0.39	−0.04 ± 0.33	0.68
Self-care	0 ± 0	0 ± 0	NA	−0.05 ± 0.44	−0.05 ± 0.45	0.79	0.01 ± 0.37	0.01 ± 0.39	0.99	0.07 ± 0.47	−0.08 ± 0.34	0.02	0 ± 0.49	−0.04 ± 0.43	0.52
Usual activities	0 ± 0.53	0.11 ± 0.33	0.66	0 ± 0.44	−0.05 ± =0.45	0.61	−0.03 ± 0.52	−0.04 ± 0.35	0.94	0.05 ± 0.40	0.02 ± 0.43	0.68	0.08 ± 0.48	0 ± 0.27	0.64
Pain discomfort	0.13 ± 0.35	0 ± 0.5	0.61	0.02 ± 0.47	0 ± 0.39	0.8	0.06 ± 0.45	−0.05 ± 0.43	0.13	0 ± 0.43	−0.08 ± 0.44	0.35	0.04 ± 0.34	−0.04 ± 0.51	0.54
Anxiety	−0.13 ± 0.35	−0.22 ± 0.44	0.66	0.05 ± 0.49	−0.08 ± =0.53	0.28	−0.01 ± 0.44	−0.05 ± 0.49	0.61	0.07 ± 0.50	−0.04 ± 0.53	0.18	0.04 ± 0.34	−0.14 ± 0.65	0.09
EQ-5D VAS	3.88 ± 12.57	−1.67 ± 15.26	0.74	−1.24 ± 15.28	−0.08 ± 15.54	0.73	0.59 ± 15.27	−1.11 ± 14.95	0.51	0.09 ± 17.82	5.10 ± 18.25	0.16	2.0 ± 16.76	0.29 ± 15.25	0.70
EQ-5D index	0.03 ± 0.13	0.02 ± 0.17	1.0	0.01 ± 0.15	0.009 ± 0.15	0.66	−0.003 ± 0.11	0.01 ± 0.13	0.22	−0.002 ± 0.16	0.03 ± 0.17	0.10	−0.007 ± 0.15	0.03 ± 0.21	0.35
PAM															
Mean raw score	0.75 ± 2.66	4.56 ± 7.55	0.19	31.13 ± 14.33	28.70 ± 13.52	0.43	1.25 ± 4.76	1.23 ± 5.37	0.98	25.07 ± 15.17	26.16 ± 15.61	0.72	23.76 ± 15.69	26.01 ± 17.41	0.61
Mean activation score	3.30 ± 7.86	11.81 ± 23.54	0.33	2.18 ± 12.09	6.13 ± 14.29	0.18	4.01 ± 14.65	3.64 ± 16.50	0.89	0.44 ± 15.18	2.10 ± 15.14	0.58	12.58 ± 15.21	15.24 ± 17.29	0.55
SWAP	1.0 ± 7.80	−6.0 ± 9.25	0.11	−2.24 ± 9.87	−2.50 ± 10.13	0.91	−1.22 ± 10.64	−0.66 ± 9.25	0.74	−0.33 ± 10.57	0.20 ± 10.08	0.79	0.73 ± 13.96	1.82 ± 8.81	0.74

* Values are the mean ± SD unless indicated otherwise. PHQ-8 = 8-item Patient Health Questionnaire; PAM = Patient Activation Measure; PROMIS = Patient-Reported Outcomes Measurement Information System; VAS = visual analog scale; EQ-5D = EuroQol 5-domain instrument; SWAP = Brief Satisfaction with Appearance Scale.
† N = 41.
‡ N = 67.



	The discussion board increased my understanding of scleroderma	I made changes to my care based on recommendations from the discussion board	The discussion board environment was respectful	The discussion board addressed important issues about scleroderma
Agree	44.45%	30.87%	80.00%	67.90%
Neither Agree nor Disagree	38.27%	48.15%	11.25%	19.75%
Disagree	17.28%	20.99%	8.75%	12.34%

Figure 2. Discussion board evaluation, showing an illustration of the responses received by internet participants after completion of the 16-week randomized, controlled trial.

net group compared to the control group. Our baseline data suggest that we recruited a group of highly motivated (approximately 60% of patients 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-8 score ≥10, and PAM levels 1 and 2, we found no difference between the internet group versus the control group, although the sample sizes in these subgroups were very small and may be related to a Type II error.

Patients with chronic diseases such as SSc self-manage their illnesses on a daily basis. 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 patients with chronic diseases (8,9). Published work suggests that self-management skills are associated with improved clinical outcomes and reduce costs associated with 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 in every state in the US. Many patients with SSc have not met anyone else 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 educational programs specifically focused on scleroderma are offered via written materials, webinars, and annual conferences through the Scleroderma Foundation, and by 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 self-management in 1 site and 1 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 patients with arthritis or other 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 phe-

nomenon and ulcerations, and disability. This gap 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).

Our study also provides insight into the design of the next trial. First, it highlights the fact that the majority of the patients 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% had PAM level 4). Future studies should focus on recruiting participants with lower PAM levels (likely to be nonwhite and less-educated participants) who have lower self-efficacy scores (10), and who would likely benefit from self-management courses. Second, patients with earlier disease may benefit, because published data suggest that patients' adjustment to a chronic disease improves with time (22).

Our RCT has many strengths. We recruited and retained >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 nonacademic settings, providing generalizability for our results. Last, this is one of the largest studies evaluating a self-management or behavioral intervention in patients 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.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Khanna had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Khanna, Serrano, Silver, Cuencas, Newbill, Battyany, Maxwell, Alore, Dyas, Riggs, Connolly, Kellner, Sachdeva, Evnin, Raisch, Poole.

Acquisition of data. Khanna, Battyany, Maxwell, Alore, Dyas, Connolly, Kellner, Poole.

Analysis and interpretation of data. Khanna, Berrocal, Fisher, Bush.

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