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# Reliability, validity, and responsiveness to change of the Patient-Reported Outcomes Measurement Information System self-efficacy for managing chronic conditions measure in systemic sclerosis

**Susan L Murphy[1,2], Veronica J Berrocal[3], Janet L Poole[4] and Dinesh Khanna[5]**

## Abstract

**Objective:** The aim of this study is to examine validity, reliability, and responsiveness to change of Patient-Reported Outcomes Measurement Information System Self-Efficacy for Managing Chronic Conditions in persons with systemic sclerosis.

**Methods:** We conducted a post hoc analysis of the Patient-Reported Outcomes Measurement Information System Self-Efficacy measure and other quality-of-life measures from systemic sclerosis participants from a 16-week randomized control trial. The trial compared an Internet-based self-management program to a control condition where participants were provided an educational book. All participants completed outcome measures at baseline and following the 16-week trial period.

**Results:** The mean age of participants was 53.7 years, 91% were female and systemic sclerosis subtype included 44.9% limited/sine and 43.1% diffuse; mean disease duration was 9.0 years. All self-efficacy subscales (Managing Emotions, Symptoms, Daily Activities, Social Interactions, and Medications/Treatment) demonstrated good internal consistency (.92–.96). All subscales showed statistically significant correlations with other validated measures of depressive symptoms and quality of life (.20–.86) but were not associated with satisfaction nor with appearance. The subscales appropriately discriminated between those with and without depressive symptoms and demonstrated responsiveness to change over the 16-week period for those who had a corresponding increase in reported quality of life.

**Conclusion:** The Patient-Reported Outcomes Measurement Information System Self-Efficacy measure is valid, reliable, and responsive to change for persons with systemic sclerosis.

**Keywords**

Systemic sclerosis, self-efficacy, Patient-Reported Outcomes Measurement Information System

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## Introduction

Systemic sclerosis (SSc) is a rare multi-organ autoimmune disease that universally affects the skin, and involves a complex interplay between inflammation, fibrosis, and vasculopathy.[1,2] There is currently no cure. SSc has the highest mortality rate among rheumatic diseases. Due to hand contractures, fatigue, poor sleep, low self-esteem, pain, and Raynaud's phenomenon caused by SSc, it is associated with significant functional and work disability, and often significantly decreases quality of life.[3] For persons with SSc, self-efficacy is an important attribute that aids management of their condition. Self-efficacy is confidence in ability to perform a behavior needed to reach a goal, even when a situation is unpredictable or stressful.[4] Self-efficacy is a key mediator of attaining self-management skills in chronic diseases such as SSc.[5,6] Thus, relevant measures of SSc are important for clinical trials to examine behavior change supporting self-management.

The Patient-Reported Outcomes Measurement Information System (PROMIS) Self-Efficacy for Managing Chronic Conditions measure[7] covers five domains, including confidence in (1) managing symptoms and preventing symptoms from interfering with activities; (2) performing specific tasks or behaviors of daily living without assistance; (3) understanding and taking medications and treatments; (4) handling negative emotions, stress, and anxiety; and (5) maintaining social activities and getting support from others. However, reliability, validity, and responsiveness to change for the PROMIS Self-Efficacy measure have not been examined for persons with SSc. We examined these psychometric properties using data from a previous SSc Internet-based randomized controlled trial.[8]

## Methods

For this post hoc analysis, we included participants (N = 267) who completed post-intervention questionnaires after participating in a 16-week trial.[8] Trial design and outcomes have been published previously.[8] Briefly, we recruited participants with SSc from scleroderma clinics, as well as participants with self-identified SSc from online sources via Scleroderma Foundation and Scleroderma Research Foundation. Participants provided web-based written informed consent and were randomized to either Internet-based program or educational book condition. Participants in the Internet program focused on one SSc-related module weekly (15 modules total) and engaged with other participants through online discussion board. Participants in the control group received *The Scleroderma Book: A Guide for Patients and Families*, by Dr. Maureen Mayes. The study was approved by institutional human subjects review boards at University of New Mexico, University of Michigan, and Medical University of South Carolina.

### Measures

We collected demographics: age, sex, race, ethnicity, education level, marital status, employment status, SSc type (diffuse, limited/sine, overlap), length of time since disease onset, and self-rated health. All other measures were assessed at baseline and 16 weeks.

We used the PROMIS Self-Efficacy for Managing Chronic Conditions measure[6] to assess self-efficacy. This measure comprises five domains: Managing Emotions, Managing Symptoms, Managing Daily Activities, Managing Social Interactions, and Managing Medications and Treatments. Each eight-item domain is scored from 1 (*not at all confident*) to 5 (*very confident*). Scales are standardized on a T metric, where 50 is the mean for the US population and standard deviation (SD) is 10. Higher T scores indicate greater self-efficacy.

Participants completed the PROMIS-29 v2.0.[9] This measure has seven domains: Physical Function, Anxiety, Depression, Fatigue, Sleep Disturbance, Pain Interference, and Satisfaction with Social Roles (four items in each domain), and one visual analogue scale on Pain Intensity. Participants scored items from 1 (unable to do/never/not at all) to 5 (without any difficulty/always/very much). Scores were standardized on a T metric.

The Patient Health Questionnaire–8 (PHQ-8)[10] was used to assess depressive symptoms. It has eight items scored from 0 (*not at all*) to 3 (*nearly every day*); a score $\geq 10$ indicates depressed mood. European Quality of Life–Five Dimensions (EQ-5D)[11] assessed health-related quality of life. It comprises five domains: Mobility, Self-Care, Activity, Pain, and Anxiety. Participants rated themselves on a scale of no to extreme problems. Using an algorithm, responses were converted into a utility measure ranging from 0 to 1.0 (full/optimal health). In addition to domain scores, we calculated the EQ-5D overall index. Participants rated their health on a visual analogue scale (from worst to best health you can imagine). The 13-item Patient Activation Measure (PAM)[12] assessed patient knowledge, skill, and confidence for self-management and is scored from 1 (*strongly disagree*) to 4 (*strongly agree*). We summed scores and transformed the summed score into a 0- to 100-point scale. Higher scores indicate greater confidence in managing their condition.

We used the Brief Satisfaction with Appearance Scale (SWAP) to assess participants' body image concerns, a reliable and valid measure for persons with SSc.[13] Participants rated their feelings related to six items about their appearance on a scale from 1 (*strongly disagree*) to 7 (*strongly agree*). Total score ranges from 0 to 36; higher scores are associated with greater body image dissatisfaction.

### Statistical analysis

As reported previously,[8] there were no significant differences in primary and most secondary outcomes between intervention and control groups. Therefore, we analyzed data for all participants combined regardless of treatment assignment. Summary statistics were calculated for demographic variables and outcome measures. Continuous variables are reported as mean and SDs, and frequencies are reported for categorical variables.

To assess floor and ceiling effects, we determined minimum and maximum scores for all subscales and assessed number and percentage of participants achieving minimum and maximum scores in each subscale at baseline. We also assessed internal consistency by computing Cronbach's alpha[14] for all subscales at baseline; Cronbach's $\alpha$ of $\geqslant 0.70$ is acceptable internal consistency.[15]

To determine whether there was an association between Self-Efficacy subscales and other quality-of-life measures at baseline, we calculated Pearson's correlations between subscales and PHQ-8, PROMIS-29 subscales (plus visual analogue scale), EQ-5D (all subscales, summary index, and visual analogue scale), PAM raw and activation scores, and Brief SWAP. We interpreted strength of association as 0.0–0.25 = little/no association, 0.25–0.50 = fair, 0.50–0.75 = moderate to good, and >0.75 = good to excellent.[16]

To determine whether the subscales can discriminate between participants, we compared baseline subscale scores in participants with the following demographics: (1) race (White vs any other race), (2) education (high school vs greater than high school), (3) marital status (married vs others), (4) employment status (full-time employee vs others), (5) SSc type (diffuse vs limited/sine), (6) length of time since disease onset of first SSc symptoms (greater vs less than median duration), (7) length of time since disease onset of first symptoms (>5 vs ⩽5 years), and (8) depression (PHQ-8 score ⩾10 vs <10). The p values ⩽.05 were considered statistically significant; no adjustment was made for multiple testing.

We assessed responsiveness to change in PROMIS Self-Efficacy subscales from baseline to 16 weeks relative to change in health-related quality of life (EQ-5D) over that time. For EQ-5D overall index, we compared those whose EQ-5D had an increase in quality of life, as indicated by improvement of ⩾0.05 over time versus all others. For each group, effect size was calculated by deriving average change in each subscale score from baseline to 16 weeks and dividing it by baseline SD. We used Cohen's interpretation of effect sizes (0.20–0.49 = small change, 0.50–0.79 = medium, and ⩾0.80 = large change).[16]

## Results

Participants had a mean (SD) age of 53.7 (11.7) years, 91% were female, 82.8% were White, and 77.5% were non-Hispanic (Table 1). In addition, 79.4% completed at least some college or beyond, 63.7% were married, and 35.6% were working full-time. For SSc types, more participants

**Table 1.** Baseline characteristics (N = 267).

| Measures | Values |
|---|---|
| Age, mean (SD) in years | 53.7 (11.7) |
| Sex, % (n) | |
| Male | 9 (24) |
| Female | 91 (243) |
| Race, % (n) | |
| White | 82.8 (221) |
| African American | 7.5 (20) |
| Asian/Asian American | 1.5 (4) |
| Native Hawaiian or Other Pacific Islander | 0.7 (2) |
| Native American/Alaskan Native | 0.4 (1) |
| Other | 1.1 (3) |
| Multiracial | 6.0 (16) |
| Ethnicity, % (n) | |
| Hispanic | 4.1 (11) |
| Non-Hispanic | 77.5 (207) |
| Other | 15.0 (40) |
| Unknown | 3.4 (9) |
| Education, % (n) | |
| Primary education (0–8 years) | 0.0 (0) |
| High school (9–12 years) | 20.6 (55) |
| College/university (13–16 years) | 48.3 (129) |
| Graduate school or higher (17+ years) | 31.1 (83) |
| Marital status, % (n) | |
| Single | 11.6 (31) |
| Married | 63.7 (170) |
| Widowed | 3.4 (9) |
| Divorced/separated | 21.3 (57) |
| Employment status, % (n) | |
| Working full-time (⩾20 h per week) | 35.6 (95) |
| Working part-time (<20 h per week) | 6.7 (18) |
| Disability or sick leave | 26.2 (70) |
| Retired | 22.1 (59) |
| Other | 9.4 (25) |
| Self-defined SSc subtype, % (n) | |
| Limited/sine SSc | 44.9 (120) |
| Diffuse SSc | 43.1 (115) |
| Overlap disease | 11.6 (31) |
| Unknown | 0.4 (1) |
| Disease duration, mean (SD) in years | |
| After first diagnosis from doctor | 9.0 (8.5) |
| After first scleroderma symptom | 11.9 (10.1) |
| Overall health, % (n) | |
| Excellent | 1.1 (3) |
| Very good | 12.4 (33) |
| Good | 42.7 (114) |
| Fair | 37.4 (100) |
| Poor | 6.4 (17) |
| PROMIS self-efficacy, mean (SD) | |
| Managing Emotions | 46.6 (9.0) |
| Managing Symptoms | 47.5 (8.5) |
| Managing Daily Activities | 44.8 (7.2) |
| Managing Social Interactions | 46.6 (9.3) |
| Managing Medications and Treatments | 49.7 (8.7) |

SD: standard deviation; SSc: systemic sclerosis; PROMIS: Patient-Reported Outcomes Measurement Information System.

**Table 2.** Floor/ceiling effects and reliability for PROMIS self-efficacy subscales at baseline (N = 267).

| PROMIS Self-Efficacy scales | Minimum score | Maximum score | % with minimum score | % with maximum score | Cronbach's α |
|---|---|---|---|---|---|
| Managing Emotions | 23.0 | 64.7 | 0 | 8 | 0.96 |
| Managing Symptoms | 23.2 | 63.5 | 0 | 11 | 0.94 |
| Managing Daily Activities | 24.9 | 60.8 | 0 | 9 | 0.92 |
| Managing Social Interactions | 20.2 | 59.8 | 1 | 24 | 0.93 |
| Managing Medications and Treatments | 23.0 | 60.6 | 0 | 24 | 0.92 |

PROMIS: Patient-Reported Outcomes Measurement Information System.

had limited/sine SSc (45%) compared to diffuse (43%). Mean (SD) participant-reported disease duration after diagnosis was 9.0 (8.5) years. Most participants rated their overall health as "Good" at 43%. Baseline mean for the subscales ranged from 44.6 to 49.7—slightly lower than the standardized mean of 50 for the US population.

Table 2 shows the possible minimum and maximum scores for PROMIS Self-Efficacy subscales. The lowest possible subscale scores ranged from 20.2 to 24.9; highest possible scores ranged from 59.8 to 64.7. At baseline, no participants had the lowest score for four of the subscales (Managing Emotions, Symptoms, Daily Activities, Medications/Treatment). Only 1% of participants scored the lowest possible score for Managing Social Interactions, indicating no floor effects. However, some participants did have maximum possible scores for each subscale (range: 8%–24%), meaning they had high self-efficacy in managing the respective areas. Cronbach's alpha for all subscales ranged from 0.92 to 0.96, indicating high and acceptable reliability for all subscales.

Table 3 shows the PROMIS Self-Efficacy subscales had fair to good associations with each other (0.35–0.67). Correlation coefficients between subscales and other quality-of-life measures ranged from little to excellent range. The subscales had little to good negative correlations with most PROMIS-29 subscales (–0.16 to –0.71). Managing Emotions had especially good negative correlations with PROMIS-29 Anxiety (–0.71) and Depression (–0.68) subscales. The subscales were positively correlated with PROMIS-29 Physical Function subscale, with an excellent correlation between that and Managing Daily Activities subscale (0.79). The subscales had fair negative correlations with the PHQ-8 (–0.28 to –0.44). They also had little to moderate correlations with EQ-5D index and visual analogue scale (0.24–0.58), and little to moderate correlations with PAM (0.38–0.65). However, subscales were not correlated with Brief SWAP (–0.02 to –0.10).

Table 4 shows that PROMIS Self-Efficacy subscales did differ by some demographics, but not all. There were no differences in subscale scores by race, education, or SSc type. The only subscale that differed by marital status was Managing Social Interactions, with those married (47.9) having higher self-efficacy than those not married (44.3, $p < 0.001$). Several subscales differed by employment status. Those who worked full-time had greater self-efficacy in managing symptoms (49.5), daily activities (47.3), and medications and treatments (51.2), compared with those who were not working full-time (46.4, $p = .005$; 43.4, $p = 0.001$; and 48.9, $p = 0.03$, respectively). One subscale (Managing Social Interactions) also differed by disease duration. Those who first experienced their SSc symptoms >5 years ago actually had lower self-efficacy to manage social interactions (45.8) compared to those who had first experienced symptoms ⩽5 years ago (48.2, $p = 0.04$). All subscales showed discriminant validity when comparing scores between t hose who had PHQ-8 scores ⩾10 (indicating depressed mood) and those who had lower scores. Those without depressive symptoms had higher self-efficacy scores in all five areas compared to those who had depressive symptoms ($p = 0.006$–$0.01$).

Four subscales showed expected change over time, corresponding to reported change in quality of life on EQ-5D from baseline to 16 weeks (Table 5). For participants who reported increased quality of life over time (EQ-5D > 0.05), they also reported an increase in self-efficacy for managing emotions, symptoms, daily activities, and social interactions. Effect sizes for these changes were small (0.23–0.33). These participants did not have increased self-efficacy to manage medications and treatments. Comparatively, participants who have increased quality of life over time also did not have an increase in self-efficacy, as expected.

## Discussion

Persons with SSc have many activities they need to perform daily to manage their condition. Self-efficacy is an important attribute for persons with SSc and other chronic conditions[17] because having confidence to manage their condition is known to have positive impacts on chronic disease–related outcomes.[5,6] Self-management skills are associated with improved clinical outcomes,[17] so self-efficacy is often a target for intervention.

The PROMIS Self-Efficacy measure was shown to be reliable and valid in this study. These findings align with another study in a broad subject sample that found this measure to be feasible, reliable, and valid.[7] All five subscales demonstrated good internal consistency, and showed

**Table 3.** Correlation analyses between PROMIS self-efficacy subscales and other quality-of-life scales.

| | P-29 Social Role | P-29 Anxiety | P-29 Depression | P-29 Fatigue | P-29 Pain Interference | P-29 Pain Intensity | P-29 Sleep Disturbance | P-29 Physical Function | Self-Efficacy Emotion | Self-Efficacy Symptoms | Self-Efficacy Daily Activities | Self-Efficacy Social Interaction | Self-Efficacy Medications and Treatments | EQ-5D VAS | EQ-5D Index | PAM Activation Score | SWAP |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PHQ-8 | 0.44*** | 0.56*** | 0.57*** | 0.49*** | 0.41*** | 0.34*** | 0.38*** | –0.36*** | –0.44*** | –0.38*** | –0.41*** | –0.28*** | –0.28*** | –0.45 *** | –0.46*** | –0.28*** | 0.08 |
| PROMIS-29 Social Role | | 0.46*** | 0.51*** | 0.69*** | 0.61*** | 0.46*** | 0.33*** | –0.65*** | –0.44*** | –0.64*** | –0.66*** | –0.37*** | –0.33*** | –0.52 *** | –0.60*** | –0.49*** | 0.09 |
| PROMIS-29 Anxiety | | | 0.81*** | 0.52*** | 0.41*** | 0.34*** | 0.33*** | –0.26*** | –0.71*** | –0.54*** | –0.35*** | –0.48*** | –0.46*** | –0.44 *** | –0.51*** | –0.49*** | 0.10 |
| PROMIS-29 Depression | | | | 0.50*** | 0.43*** | 0.36*** | 0.32*** | –0.33*** | –0.68*** | –0.51*** | –0.40*** | –0.47*** | –0.42*** | –0.45 *** | –0.55*** | –0.47*** | 0.10 |
| PROMIS-29 Fatigue | | | | | 0.62*** | 0.50*** | 0.43*** | –0.50*** | –0.46*** | –0.53*** | –0.55*** | –0.33*** | –0.23*** | –0.50*** | –0.53*** | –0.41*** | 0.10 |
| PROMIS-29 Pain Interference | | | | | | 0.86*** | 0.40*** | –0.58*** | –0.34*** | –0.51*** | –0.59*** | –0.26*** | –0.25*** | –0.41*** | –0.62*** | –0.36*** | 0.14* |
| PROMIS-29 Pain Intensity | | | | | | | 0.37*** | –0.50*** | –0.25*** | –0.38*** | –0.49*** | –0.16*** | –0.19** | –0.34*** | –0.58*** | –0.23*** | 0.17** |
| PROMIS-29 Sleep Disturbance | | | | | | | | –0.34*** | –0.35*** | –0.37*** | –0.39*** | –0.21*** | –0.20** | –0.34*** | –0.37*** | –0.28*** | 0.08 |
| PROMIS-29 Physical Function | | | | | | | | | 0.27*** | 0.52*** | 0.79*** | 0.22*** | 0.26*** | 0.49*** | 0.55*** | 0.37*** | –0.15* |
| Self-Efficacy Emotion | | | | | | | | | | 0.67*** | 0.47*** | 0.59*** | 0.56*** | 0.43*** | 0.42*** | 0.54*** | –0.02 |
| Self-Efficacy Symptoms | | | | | | | | | | | 0.67*** | 0.60*** | 0.58*** | 0.43*** | 0.48*** | 0.65*** | –0.07 |
| Self-Efficacy Daily Activities | | | | | | | | | | | | 0.35*** | 0.43*** | 0.50*** | 0.58*** | 0.38*** | –0.10 |
| Self-Efficacy Social Interactions | | | | | | | | | | | | | 0.62*** | 0.30*** | 0.24*** | 0.58*** | –0.05 |
| Self-Efficacy Medications and Treatments | | | | | | | | | | | | | | 0.28*** | 0.27*** | 0.57*** | –0.08 |
| EQ-5D VAS | | | | | | | | | | | | | | | 0.51*** | 0.35*** | –0.12 |
| EQ-5D Index | | | | | | | | | | | | | | | | 0.35*** | –0.09 |
| PAM Activation score | | | | | | | | | | | | | | | | | –0.09 |

PROMIS: Patient-Reported Outcomes Measurement Information System; EQ-5D: European Quality of Life–Five Dimensions; VAS: Visual Analogue Scale; PAM: Patient Activation Measure; SWAP: Satisfaction with Appearance Scale; PHQ-8: Patient Health Questionnaire–8.

*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$.

**Table 4.** Discrimination of PROMIS self-efficacy subscales by demographics.

| Scales, mean (SD) | Managing Emotions | Managing Symptoms | Managing Daily Activities | Managing Social Interactions | Managing Medications and Treatments |
|---|---|---|---|---|---|
| All (n = 267) | 46.6 (9.0) | 47.5 (8.5) | 44.8 (7.2) | 46.6 (9.3) | 49.7 (8.7) |
| White (n = 236) | 46.50 (8.8) | 47.17 (8.3) | 44.83 (7.2) | 46.56 (9.4) | 49.6 (8.6) |
| Others (n = 31) | 47.1 (11.0) | 49.94 (9.6) | 44.4 (6.9) | 47.1 (8.9) | 50.7 (9.5) |
| p value | 0.94 | 0.09 | 0.99 | 0.66 | 0.40 |
| ≤High school (n = 55) | 46.2 (10.6) | 47.7 (10.2) | 43.19 (7.4) | 47.9 (11.0) | 48.1 (10.2) |
| >High school (n = 212) | 46.7 (8.6) | 47.5 (8.1) | 45.18 (7.1) | 46.3 (8.9) | 50.2 (8.2) |
| p value | 0.84 | 0.67 | 0.09 | 0.14 | 0.32 |
| Married (n = 170) | 47.1 (8.8) | 47.72 (8.3) | 45.2 (7.3) | 47.9 (9.5) | 49.7 (8.4) |
| Others (n = 97) | 45.6 (9.4) | 47.1 (8.8) | 44.1 (7.0) | 44.3 (8.7) | 49.8 (9.2) |
| p value | 0.3 | 0.41 | 0.17 | 0.0007 | 0.83 |
| Full-time work (n = 95) | 47.8 (8.8) | 49.5 (8.4) | 47.3 (6.7) | 47.8 (9.8) | 51.2 (9.0) |
| Others (n = 172) | 45.9 (9.1) | 46.4 (8.4) | 43.4 (7.1) | 46.0 (9.1) | 48.9 (8.4) |
| p value | 0.1 | 0.005 | 0.001 | 0.13 | 0.03 |
| Limited/sine (n = 120) | 46.0 (8.8) | 47.3 (7.9) | 45.6 (7.5) | 45.83 (9.8) | 48.8 (8.9) |
| Diffuse (n = 115) | 47.3 (9.3) | 48.4 (8.8) | 44.4 (6.7) | 47.96 (8.8) | 50.7 (8.5) |
| p value | 0.48 | 0.42 | 0.19 | 0.09 | 0.11 |
| Disease duration ≤5 years (n = 92) | 47.3 (9.1) | 48.8 (8.2) | 45.5 (7.0) | 48.2 (9.0) | 50.1 (8.6) |
| Disease duration >5 years (n = 175) | 46.2 (9.0) | 48.6 (8.6) | 44.4 (7.3) | 45.8 (9.4) | 49.5 (8.7) |
| p value | 0.46 | 0.08 | 0.12 | 0.04 | 0.57 |
| PHQ-8 ≥ 10 (n = 115) | 44.0 (9.1) | 45.7 (8.6) | 42.9 (6.1) | 44.9 (9.1) | 48.1 (9.0) |
| PHQ-8 < 10 (n = 152) | 48.5 (8.5) | 48.9 (8.2) | 46.2 (7.6) | 47.9 (9.4) | 50.9 (8.3) |
| p value | 0.001 | 0.002 | 0.001 | 0.01 | 0.006 |

PROMIS: Patient-Reported Outcomes Measurement Information System; SD: standard deviation; PHQ-8: The Patient Health Questionnaire–8.

**Table 5.** Responsiveness to change for PROMIS self-efficacy subscales.

| PROMIS Self-Efficacy scales, mean (SD) | Change of EQ-5D > 0.05 (n = 56) | Effect size | Change of EQ-5D ≤ 0.05 (n = 159) | Effect size |
|---|---|---|---|---|
| Managing Emotions | 2.4 (8.6) | 0.26 | –0.5 (7.2) | –0.06 |
| Managing Symptoms | 3.0 (7.3) | 0.33 | 0.3 (6.6) | 0.03 |
| Managing Daily Activities | 1.4 (6.6) | 0.23 | –0.1 (5.0) | –0.02 |
| Managing Social Interactions | 2.7 (7.7) | 0.30 | 0.3 (8.1) | 0.03 |
| Managing Medications and Treatments | 0.6 (8.6) | 0.07 | –0.5 (8.3) | –0.06 |

PROMIS: Patient-Reported Outcomes Measurement Information System; SD: standard deviation; EQ-5D: European Quality of Life–Five Dimensions.

moderate to large correlations with other validated measures of depressive symptoms and quality of life, but they were not associated with satisfaction with appearance. The subscales appropriately discriminated between those with and without depressive symptoms and demonstrated responsiveness to change over 16 weeks for those who had a corresponding increase in reported quality of life.

This study has many strengths. We used prospective data from one of the largest self-management trials to date involving a national sample of SSc participants.[8] We validated the subscales for persons with SSc by demonstrating strong associations with several common patient-reported quality-of-life measurements. Our analysis showed that the Self-Efficacy subscales were able to discriminate between participants with and without depressive symptoms, supporting validity of the subscales in SSc. One limitation is that all data were self-reported. Thus, we could not confirm their reported disease characteristics. However, for self-perceived measures such as self-efficacy, patient-reported outcomes are likely more applicable and important when determining reliability and validity. Also, we had a relatively short observation period in this study—16 weeks—and a longer observation period may be needed in future validation studies. Effect sizes for responsiveness to change were modest which may be due in part to the length of the observation period or to the lack of effect of the intervention on self-efficacy outcomes.[8] Future validation studies can also incorporate evaluation of additional disability and functioning measures, beyond the EQ-5D measure in this study.

In conclusion, we demonstrated that the PROMIS Self-Efficacy for Managing Chronic Conditions scale is valid, reliable, and responsive to change for persons with SSc. This study provides support for the use of this scale as a outcome measure in clinical trials.

## Authors' note

The Editor/Editorial Board Member of *Journal of Scleroderma and Related Disorders* (*JSRD*) is an author of this paper; therefore, the peer review process was managed by alternative members of the Board, and the submitting Editor/Board member had no involvement in the decision-making process.

## Declaration of conflicting interests

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