

Self-Efficacy for Managing Chronic Disease Scale for Scleroderma

Validation of the Self-Efficacy for Managing Chronic Disease (SEMCD) Scale: A Scleroderma Patient-centered Intervention Network (SPIN) Cohort Study

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ABSTRACT

Objective: Self-management programs for patients with chronic illnesses, including rheumatic diseases, seek to enhance self-efficacy for performing health management behaviors. No measure of self-efficacy has been validated for patients with systemic sclerosis (SSc). The objective of this study was to assess the validity and internal consistency reliability of the Self-Efficacy for Managing Chronic Disease (SEMCD) Scale in SSc.

Methods: English-speaking SSc patients enrolled in the Scleroderma Patient-centered Intervention Network Cohort who completed the SEMCD Scale at their baseline assessment between March 2014 and June 2015 were included. Patients were enrolled from 21 sites in Canada, the United States and the United Kingdom. Confirmatory factor analysis (CFA) was used to evaluate the factor structure of the SEMCD Scale. Cronbach's alpha was calculated to assess internal consistency reliability. Hypotheses on the direction and magnitude of Pearson's correlations with psychological and physical outcome measures were formulated and tested to examine convergent validity.

Results: A total of 553 patients were included. CFA supported the single-factor structure of the SEMCD Scale (Tucker Lewis Index = 0.99, Comparative Fit Index = 0.99, Root Mean Square Error of Approximation = 0.10). Internal consistency was high ($\alpha = 0.93$), and correlations with measures of psychological and physical functioning were moderate to large ($|r| = 0.48 - 0.67$, $P < 0.001$), confirming study hypotheses.

Conclusion: Scores from the SEMCD Scale are valid for measuring self-efficacy in patients with SSc, and results support using the scale as an outcome measure to evaluate the effectiveness of self-management programs in SSc.

128 **SIGNIFICANCE AND INNOVATION**

- 129 • The enhancement of self-efficacy is a key goal of self-management programs for patients
130 with chronic illnesses, including rheumatic diseases, but prior to this study no
131 measurement scales had been validated for systemic sclerosis (SSc).
- 132 • We found that the Self-Efficacy for Managing Chronic Disease (SEMCD) Scale had good
133 reliability and validity and that results for patients with SSc were similar to results from
134 patients with other chronic diseases in previous studies.
- 135 • The SEMCD Scale can be used to evaluate self-efficacy in patients with SSc, including as
136 an outcome measure in trials of self-management programs.

INTRODUCTION

Self-management programs are increasingly emphasized as a cost-effective way to involve patients in managing their own chronic illness (1). Although self-management programs have been designed for many different medical conditions and target a range of symptoms, virtually all seek to enhance self-efficacy, or an individual's perceived confidence to perform specific health management behaviors. A Cochrane Review of 17 randomized controlled trials and 7,442 patients found that self-management programs significantly increased self-efficacy compared to usual care (standardized mean difference = 0.30, 95% confidence interval 0.19 – 0.41) (1).

The Self-Efficacy for Managing Chronic Disease (SEMCD) Scale is a 6-item questionnaire that measures confidence in one's ability to manage fatigue, pain, emotional distress, and other symptoms using self-management techniques (2). The SEMCD has been used extensively as an outcome measure in trials evaluating self-management programs, and the English-language version was validated in six large samples of patients with chronic conditions enrolled in studies of self-management programs (2).

Systemic sclerosis (SSc; scleroderma) is a rare multisystem autoimmune disease that affects the skin and internal organs. The Scleroderma Patient-centered Intervention Network (SPIN) was created to develop and disseminate accessible internet-based interventions tailored to the needs of SSc patients, including a self-management program (3). Although patients with rare diseases, including SSc, often face unique self-management challenges, they share many key self-management outcomes. For instance, similar to patients with more common diseases, patients with SSc live with chronic fatigue, pain, and a high level of functional disability, which can lead to emotional distress and reduced quality of life (3). At present, however, there is no measure of self-efficacy validated for patients with SSc. The objective of the present study was

to replicate previous validation studies in other diseases and assess the validity of the SEMCD Scale in SSc.

PATIENTS AND METHODS

Patients and Procedure

The sample consisted of patients enrolled in the SPIN Cohort (3) who completed study questionnaires from March 2014 through June 2015. Patients were enrolled at 21 centers from Canada, the USA, and the UK. To be eligible, patients must have a confirmed diagnosis of SSc according to 2013 ACR/EULAR criteria (4), be ≥ 18 years of age, have the ability to give informed consent, be fluent in English or French, and have access and be able to respond to questionnaires via the Internet. The SPIN sample is a convenience sample. Eligible patients are invited by attending physicians or supervised nurse coordinators from SPIN centers to participate, and written informed consent is obtained. The local SPIN investigator completes a medical data form that is submitted online to initiate patient registration, which triggers the sending of an automated welcoming email to participants with instructions for activating their SPIN account and completing SPIN Cohort measures online. SPIN Cohort patients complete outcome measures via the Internet upon enrollment and subsequently every 3 months. Patients who completed the SEMCD Scale at baseline in English were included in the present study. The SPIN Cohort study was approved by the Research Ethics Committee of the Jewish General Hospital, Montréal, Canada and by the research ethics committees of each participating center.

Measures

Patients provided demographic data. SPIN physicians provided medical information, including time since first non-Raynaud's phenomenon symptoms, SSc subtype (limited or

diffuse), modified Rodnan skin score, and presence of autoantibodies (anti-nuclear antibody, anti-centromere antibody, anti-topoisomerase I, and anti-RNA polymerase III).

The 6-item SEMCD Scale (2) measures respondents' confidence in their ability to manage fatigue, pain, emotional distress and other symptoms, to do things other than take medication to reduce illness impact, and to carry out tasks and activities that may reduce the need to see a doctor. Respondents are asked to rate their confidence that they can perform certain tasks regularly at the present time. Items are rated on a numerical scale ranging from 1 (*not confident at all*) to 10 (*totally confident*). The score for the scale is the mean of all items, with higher scores reflecting greater self-efficacy. The measurement properties of the English-language version of the SEMCD Scale were examined in data aggregated from six studies that included 2,866 patients with various chronic illnesses (2). Principal component analyses confirmed that the measure had a one-dimensional structure. Internal consistency was high across the six studies (Cronbach's alpha 0.87 – 0.91), and moderate correlations were obtained with SEMCD scores and measures of health outcomes, including health distress, illness intrusiveness, activity limitation, depression, and fatigue (2).

Patient-reported health status was measured using the 29-item Patient Reported Outcomes Measurement Information System (PROMIS-29) profile version 2.0. The PROMIS-29 measures eight domains of health status over the past 7 days with 4 items for each of 7 domains (physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles and activities, pain interference) plus a single item for pain intensity. Each item is scored on a 5-point scale, ranging from 1 to 5, with different response options for different domains, except for the item measuring pain intensity (11-point rating scale, ranging from 0 (*no pain*) to 10 (*worst imaginable pain*)). Higher scores represent more of the domain being measured; that is,

better physical function and ability to participate in social roles and activities, but higher levels of anxiety, depression, fatigue, sleep disturbance, pain interference, and pain intensity. Total raw scores are obtained by summing item scores for each domain, which are then converted into T-scores standardized from the general US population (mean = 50, standard deviation [SD] = 10). The PROMIS-29 is a valid measure of health status in patients with SSc (5).

Symptoms of depression were measured using the 8-item Patient Health Questionnaire (PHQ-8) (6). The PHQ-8 items measure depressive symptoms over the last 2 weeks on a 4-point scale, ranging from 0 (*not at all*) to 3 (*nearly every day*). A total score is obtained by summing item scores, with higher scores indicating more depressive symptoms. The PHQ-8 performs equivalently to the PHQ-9 (6), which is a valid measure of depressive symptoms in patients with SSc (7).

Functional disability was measured using the Disability Index of the Health Assessment Questionnaire (HAQ-DI). The HAQ-DI assesses 8 disability categories over the past 7 days: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and common daily activities. Each item is rated on a 4-point scale, ranging from 0 (*without any difficulty*) to 3 (*unable to do*), with higher scores indicating greater functional disability. The highest score from each category determines the score for that category, and the total score is the mean of the 8 category scores, ranging from 0 (*no disability*) to 3 (*severe disability*). The HAQ-DI is widely used in patients with rheumatologic diseases and is a valid measure of functional disability in SSc (8).

Statistical Analyses

Means, SDs, item intercorrelations, and corrected item-total correlations (correlation of item score with total score after removing the item from the total score) were calculated for each SEMCD item, and the mean and SD were calculated for the total score. Floor and ceiling effects

were defined as $\geq 15\%$ of participants having the lowest or highest possible score, respectively (9). Internal consistency was assessed with Cronbach's alpha. Confirmatory factor analysis (CFA) was conducted to confirm the single-factor structure of the SEMCD Scale (2). Item responses for the SEMCD are ordinal Likert data and therefore modeled using MPlus with the weighted least squares estimator and a diagonal weight matrix, robust standard errors, and a mean- and variance-adjusted chi-square statistic with delta parameterization. The chi-square test, Tucker-Lewis Index (TLI), Comparative Fit Index (CFI) and Root Mean Square Error of Approximation (RMSEA) were used to assess model fit. Good fitting models are indicated by a TLI and CFI ≥ 0.95 and RMSEA ≤ 0.06 (10), although a CFI of ≥ 0.90 and a RMSEA of ≤ 0.08 (11) are often regarded as indicators of acceptable model fit. The chi-square test is highly sensitive to sample size. Therefore, the TLI, CFI and RMSEA indices were emphasized. Modification indices were used to identify pairs of items for which model fit would improve if error estimates were freed to covary and for which there appeared to be theoretically justifiable shared method effects (e.g., similar wording).

To examine convergent validity, hypotheses on the direction and magnitude of Pearson's correlations with other psychological and physical outcome measures were formulated a priori, based on existing evidence from convergent validity comparisons for the SEMCD Scale in rheumatic diseases (2), and for self-efficacy, measured with a different scale, in SSc (12). Magnitude of correlations was interpreted as small ($|r| \leq 0.3$), moderate ($0.3 < |r| < 0.5$), or large ($|r| \geq 0.5$) (13). We expected to obtain moderate to large correlations of the SEMCD Scale with all psychological and physical outcome measures.

For a one-factor CFA with 6 indicators, the minimum required sample size is estimated as between 60 and 190, assuming factor loadings between 0.50 and 0.80 (14). Stable estimates of

correlations are typically achieved with sample size of 250 or greater, although smaller correlations require larger samples. To assess a correlation with 95% confidence and a precision of 0.10, a sample size of ≥ 403 is required for $r = 0.30$, and ≥ 275 for $r = 0.50$ (15). Thus, the available number of patients was more than sufficient. CFA was conducted using MPlus 7, and all other statistical analyses were conducted using SPSS (Version 20).

RESULTS

Sample Characteristics

In total, 553 patients completed the SEMCD, including 71 men and 482 women. There were 17 patients who completed at least one other measure at the baseline assessment, but did not complete the SEMCD. All patients who submitted responses for any SEMCD item completed the full scale. Demographic and disease characteristics are shown in Table 1. Most patients (72.3%) were married or cohabitating, and 42.7% of the patients were employed. The mean \pm SD time since onset of the first non-Raynaud's symptoms was 11.6 ± 8.8 years.

Validity and Reliability of the SEMCD

The mean \pm SD SEMCD score was 6.4 ± 2.3 (median = 6.5, range 1 – 10). The mean \pm SD and corrected item-total correlations for each item are shown in Table 3. Correlations between items ranged from $r = 0.59$ ($P < 0.001$, Items 1 and 3) to $r = 0.81$ ($P < 0.001$, Items 1 and 2). Cronbach's alpha was 0.93. There were 4 patients (0.7%) who had the lowest possible score (1.0) on the scale and 30 (5.4%) with the highest possible score (10.0), suggesting that there were not substantive floor or ceiling effects.

Results of the CFA (standardized solution) are shown in Table 2. In the initial CFA, in which measurement errors between all items were specified as uncorrelated, model fit for the hypothesized single-factor model was suboptimal ($\chi^2[9] = 311.6$, $P < 0.001$, TLI = 0.96, CFI =

0.98, RMSEA = 0.25). Inspection of the modification indices indicated that model fit would be improved if the error terms of Items 1 and 2, as well as Items 5 and 6 were freed to covary. Items 1 and 2 evaluate “fatigue” and “physical discomfort or pain”, respectively, which are often closely related experiences in chronic illness. Items 5 and 6 relate to the ability to engage in activities other than taking medication to reduce the need for health care visits or to reduce the impact of the illness on everyday life. In addition to the modification indices, the conceptual overlap between each pair of items was reflected in their high inter-item correlations ($r = 0.81$, $P < 0.001$ and $r = 0.78$, $P < 0.001$, respectively). Therefore, the model was refitted to the data, allowing the error terms of these items to covary. These changes resulted in a model with a reasonably good fit to the data ($\chi^2[7] = 48.0$, $P < 0.001$, TLI = 0.99, CFI = 0.99, RMSEA = 0.10).

Given the high correlations between items 1 and 2 and 5 and 6, we conducted post-hoc analyses to evaluate a 4-item version of the SEMCD, which removed the item with the lower item-total correlation in each pair. Model fit was good ($\chi^2[2] = 4.6$, $P = 0.097$, TLI = 1.00, CFI = 1.00, RMSEA = 0.05). Cronbach’s alpha was 0.90.

As shown in Table 3, there were large correlations between the SEMCD Scale and measures of physical functioning, disability, fatigue, pain, anxiety, and depression. There was a moderate correlation with sleep disturbance. All correlations were consistent with convergent validity hypotheses. None changed substantively in post-hoc analyses.

DISCUSSION

This study assessed the validity and internal consistency reliability of the SEMCD Scale in SSc. The main finding was that the hypothesized single-factor structure of the scale fit well, supporting the use of a single total score for the SEMCD Scale. In addition, internal consistency

reliability was good, indices of convergent validity were consistent with study hypotheses, and there were no floor or ceiling effects.

The results of the present study were similar to results from a study that examined the measurement properties of the SEMCD Scale in six English-language samples of patients with various chronic illnesses (2). In that study, the SEMCD Scale was similarly found to have a single-factor structure. Results from that study's analyses of internal consistency and convergent validity with measures of depression, fatigue, and activity limitation were similar to the findings from the present study in SSc.

The results of the present study have potential implications for both researchers and clinicians. An important goal of self-management programs is to increase self-efficacy, and the SEMCD Scale has been widely used to assess this outcome. Within the context of SPIN (3), the present results support the SEMCD Scale total score as a good choice for an outcome measure to evaluate the effectiveness of its internet-based self-management intervention. More broadly, the SEMCD Scale could be used in clinical practice to evaluate the degree to which patients with SSc feel confident in successfully managing their condition or may benefit from participation in a self-management program or other supports.

The present study has limitations that should be considered in interpreting results. First, the SPIN Cohort is a convenience sample, and participants complete questionnaires online, which may limit the generalizability of findings. Second, self-efficacy was measured with a single scale, and scores were not compared to another measure of self-efficacy to further evaluate construct validity. Thirdly, since the study used cross-sectional data, it was not possible to evaluate test-retest reliability and sensitivity to change. Finally, this study documents the validation of an existing, generic measure of self-efficacy rather than the development of a

disease-specific measure. While validating an existing measure permits comparison to results from other chronic illnesses, which is important when studying rare diseases, it is possible that a disease-specific measure could better evaluate self-efficacy as it relates to SSc, specifically.

In conclusion, the results replicate findings with the SEMCD Scale in other patient groups (2) and indicate that the SEMCD Scale is a valid measure of self-efficacy in patients with SSc. The effectiveness of self-management programs is commonly evaluated using measures of self-efficacy, and the findings of this study support the use of the SEMCD Scale for this purpose in SSc.

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370 **Table 1. Patient Demographic and Disease Characteristics (N = 553)**

Sociodemographic variables	Values
Age, years, <i>mean ± SD (range)</i>	55.6 ± 11.8 (18.6 – 84.7)
Women, n (%)	482 (87)
Higher education >12 years, n (%)	446 (81)
Currently employed, n (%)	236 (43)
Married / cohabiting, n (%)	400 (73)
Time since the onset of the first non Raynaud's symptoms, years, <i>mean ± SD (range)</i> ^a	11.6 ± 8.8 (0.1 – 46.2)
Patients with diffuse systemic sclerosis ^b	230 (42)
MRSS, <i>mean ± SD (range)</i> ^c	8.1 ± 9.1 (0 – 47.0)
SEMCD score, <i>mean ± SD (range)</i>	6.4 ± 2.3 (1.0 – 10.0)
PROMIS-29	
Physical function score, <i>mean ± SD (range)</i> ^d	42.7 ± 8.6 (22.9 – 56.9)
Ability to participate in social roles and activities, <i>mean ± SD (range)</i> ^d	47.4 ± 9.6 (27.5 – 64.2)
Anxiety, <i>mean ± SD (range)</i> ^d	51.2 ± 9.7 (40.3 – 75.4)
Depression, <i>mean ± SD (range)</i> ^e	50.7 ± 9.3 (41.0 – 79.4)
Fatigue, <i>mean ± SD (range)</i> ^d	56.1 ± 10.9 (33.7 – 75.8)
Sleep disturbance, <i>mean ± SD (range)</i> ^f	52.8 ± 8.7 (32.0 – 73.3)
Pain interference, <i>mean ± SD (range)</i> ^d	56.1 ± 9.7 (41.6 – 75.6)
Pain intensity, <i>mean ± SD (range)</i> ^d	3.7 ± 2.7 (0 – 10.0)
PHQ-8 score, <i>mean ± SD (range)</i> ^g	6.2 ± 5.4 (0 – 24.0)

HAQ-DI score, *mean ± SD (range)*^d 0.8 ± 0.7 (0 – 2.9)

371 Abbreviations: MRSS = modified Rodnan skin score; SD = standard deviation; SEMCD = Self-
372 Efficacy for Managing Chronic Disease; PROMIS-29 = 29-item Patient Reported Outcomes
373 Measurement Information System; PHQ-8 = 8-item Patient Health Questionnaire; HAQ-DI =
374 Health Assessment Questionnaire Disability Index.
375
376 Due to missing values: ^an = 529; ^bn = 549; ^cn = 459; ^dn = 542; ^en = 540; ^fn = 539; ^gn = 547.

377 **Table 2. Characteristics of the Self-Efficacy for Managing Chronic Disease Scale**

Item	Mean \pm SD Score ^a	Corrected	
		Item-total Correlation	Factor Loading
1. Fatigue	5.9 \pm 2.9	0.82	0.85
2. Physical discomfort or pain	5.9 \pm 2.8	0.83	0.86
3. Emotional distress	7.0 \pm 2.6	0.73	0.81
4. Other symptoms or health problems	6.0 \pm 2.7	0.83	0.90
5. Reduce need to see doctor	6.8 \pm 2.6	0.82	0.85
6. Do things other than just taking medication	6.9 \pm 2.6	0.78	0.81
Total score	6.4 \pm 2.3		

378 ^aOn a 10-point scale, where 1 = not at all confident and 10 = totally confident.

379

Table 3. Hypotheses and correlation of variables with the Self-Efficacy for Managing Chronic Disease Scale

Convergent Validity Hypotheses ^e	Pearson's	Hypotheses	
	Correlations	<i>P</i>	Confirmed?
Moderate to large positive correlation:			
Physical function (PROMIS-29) ^a	0.60	<0.001	Yes
Ability to participate in social roles and activities (PROMIS-29) ^a	0.67	<0.001	Yes
Moderate to large negative correlation:			
Anxiety (PROMIS-29) ^a	-0.53	<0.001	Yes
Depression (PROMIS-29) ^b	-0.56	<0.001	Yes
Fatigue (PROMIS-29) ^a	-0.67	<0.001	Yes
Sleep disturbance (PROMIS-29) ^c	-0.48	<0.001	Yes
Pain interference (PROMIS-29) ^a	-0.64	<0.001	Yes
Pain intensity (PROMIS-29) ^a	-0.59	<0.001	Yes
Symptoms of depression (PHQ-8) ^d	-0.64	<0.001	Yes
Disability (HAQ-DI) ^a	-0.57	<0.001	Yes

Abbreviations: PROMIS-29 = 29-item Patient Reported Outcomes Measurement Information System; PHQ-8 = 8-item Patient Health Questionnaire; HAQ-DI = Health Assessment Questionnaire Disability Index.

Due to missing values: ^an = 542; ^bn = 540; ^cn = 539; ^dn = 547.

^eMagnitude of correlations was defined as small = $|r| \leq 0.3$, moderate = $0.3 < |r| < 0.5$, and large = $|r| \geq 0.5$.