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J Clin Epidemiol. 2016 May ; 73: 135–141. doi:10.1016/j.jclinepi.2015.08.034.**The PROMIS® Satisfaction with Social Participation Measures Demonstrate Responsiveness in Diverse Clinical Populations****Elizabeth A. Hahn¹, Jennifer L. Beaumont¹, Paul A. Pilkonis², Sofia F. Garcia¹, Susan Magasi³, Darren A. DeWalt⁴, and David Cella¹**¹Department of Medical Social Sciences, Northwestern University Feinberg School of Medicine, Chicago, IL, USA²Department of Psychiatry, University of Pittsburgh Medical Center, Pittsburgh, PA, USA³Department of Occupational Therapy, University of Illinois at Chicago, Chicago, IL, USA⁴Division of General Internal Medicine and Cecil G. Sheps Center for Health Services Research, University of North Carolina School of Medicine, Chapel Hill, NC, USA**Abstract**

Objective—To conduct a longitudinal evaluation of PROMIS® Social Function measures (Satisfaction with Participation in Social Roles, and Satisfaction with Participation in Discretionary Social Activities) in English-speaking people with chronic health conditions.

Study Design and Setting—Adults receiving treatment for chronic heart failure (CHF), chronic obstructive pulmonary disease (COPD), chronic back pain, or depression completed PROMIS computer-based measures of social health at two time points approximately three months apart, and global ratings of change. Linear mixed effects models and standardized response means were estimated for the two social function measures.

Results—A total of 599 people participated: 79 with stable COPD, 46 COPD exacerbation, 60 with CHF, 196 with depression and 218 with back pain. Four groups experienced improvement over time; one (COPD-stable) changed very little. Those who reported better global ratings of change in overall health experienced larger changes in social function than those who reported the same or worse global health.

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CONFLICT OF INTEREST

Elizabeth A. Hahn: None

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Conclusion—This study provided support for responsiveness to change for two PROMIS social function measures. These results provide further evidence of the PROMIS goal to enable comparable measurement of universally relevant symptoms and experiences that apply to people with a variety of diseases.

Keywords

PROMIS; patient-reported outcomes; social health; social function; responsiveness

INTRODUCTION

While social health has long been recognized as an integral component of health¹, it has received limited attention in clinical practice and medical research. The World Health Organization's International Classification of Functioning, Disability and Health (ICF) has helped to highlight social participation as both a determinant of health²⁻⁴ and as a treatment outcome valued by patients, providers and policy makers.⁵ Participation in social roles and discretionary activities is included in the ICF's core sets for chronic heart failure (CHF), chronic obstructive pulmonary disease (COPD), back pain and depression.⁶⁻⁸ The importance of social participation in chronic medical conditions such as these is well documented.⁹⁻¹⁴ There is, however, a need for standardized measures of social health and participation that are applicable to a broad range of conditions and clinical settings.¹⁵ The initiative titled PROMIS® (Patient-Reported Outcomes Measurement Information System) developed measures of social role performance and participation that are intended to be universally relevant, rather than disease-specific. That is, the measures are assumed relevant across many clinical populations and levels of severity, allowing for broad applicability and comparability across populations and diseases.

The PROMIS Social Health workgroup developed Social Function measures using a mixed-methods approach that included cognitive interviews, focus groups and large-scale cross-sectional testing with a general population sample.¹⁶⁻²⁰ Social Function is defined as involvement in, and satisfaction with, one's usual roles in life's situations and activities. These roles may exist in marital relationships, family responsibilities, work/school responsibilities and social activities. Item response theory methods were used to create computer adaptive tests (CAT) and fixed-length short forms.²¹⁻²⁴ This manuscript describes the longitudinal evaluation of two PROMIS Social Function CAT measures (Satisfaction with Participation in Social Roles and Satisfaction with Participation in Discretionary Social Activities) in five English-speaking clinical samples.

METHODS

Participant recruitment and assessment procedures

Five patient samples were included in four studies (COPD, CHF, Back Pain, Depression) that assessed social function. Participant recruitment procedures are described in the overview paper (Cook et al., this volume).²⁵ All participants received some type of treatment for their condition; specifically, COPD and Depression participants received treatment

appropriate for their level of disease, CHF participants received a heart transplant, and Back Pain participants received spinal injections.

Version 1.0 of the PROMIS Social Function measures includes 14 Satisfaction with Participation in Social Roles items and 12 Satisfaction with Participation in Discretionary Social Activities items. These measures refer to social roles such as work and family responsibilities, and more discretionary social activities such as leisure activity and relationships with friends. Most participants completed a CAT for both measures; CHF participants completed only one CAT (Discretionary Social Activities). Although some participants completed multiple longitudinal assessments, only two were selected for this analysis: baseline and one follow-up (at approximately three months). An assessment was scheduled at three months for most studies because some degree of clinical change was expected to have occurred by that point. For the CHF study, multiple follow-up assessments occurred after heart transplantation. The 10-week assessment was chosen for this analysis because it was closest to three months. Investigators predicted a large magnitude of improvement in both social roles and discretionary social activities for patients who were recovering from exacerbation of their COPD. They also predicted a large improvement in discretionary social activities for CHF patients after their heart transplant. Participants in the Pain and Depression groups were expected to improve in Social Function, although investigators did not have predictions about whether improvement would differ across the two aspects of Social Function (social roles vs. discretionary social activities). Participants also completed a global rating of change at the follow-up assessment.²⁶ They reported the amount of change in their overall health using a seven-point scale (very much worse, moderately worse, a little worse, about the same, a little better, moderately better, very much better). The three “better” categories and the three “worse” categories were combined to create three overall change groups: better, about the same, worse. Social function-specific change was also assessed for some participants. CHF participants reported change in their ability to carry out usual social activities and roles since their heart transplant; similar overall change groups were created as described above. COPD participants completed the PROMIS Global Health instrument.²⁷ Change groups were then calculated using the change from baseline to follow-up in responses to the PROMIS Global question: “In general, how would you rate your satisfaction with your social activities and relationships?” Some participants did not complete the global rating of change of the PROMIS Global Health instrument. Subsample sizes for each of the change groups are listed under the standardized response means in Tables 2 and 3.

Statistical analyses

Analyses to evaluate responsiveness (sensitivity to change) were conducted separately for each of five clinical groups: stable COPD, exacerbating COPD, CHF, back pain and depression. The first set of analyses evaluated change from baseline to follow-up. Linear mixed models were estimated with random subject effects to account for the correlation among repeated observations within individuals.^{28,29} Missing data were evaluated prior to performing longitudinal analyses; this included a comparison of baseline characteristics between participants with and without complete data. Assuming data were missing at random (MAR), the analyses included respondents with data at either time point.^{30,31} Least

squares means, standard errors and 95% confidence intervals were estimated from the models.

The second set of analyses evaluated change in the PROMIS measures in relation to participants' self-reported change. Only participants with data at both time points and with a response to the self-reported change item were included in these analyses. Change scores in the CAT measures were used to estimate the standardized response mean for each of the three change groups: the ratio of the mean change to the standard deviation of that change.³² This is a form of Cohen's effect size index.³³ An effect size of 0.30 is generally considered as a useful criterion for a minimally important difference in patient-reported outcome measures.³⁴

RESULTS

Participant characteristics

A total of 599 people participated in the clinical studies that assessed Social Function. Participants were diverse in terms of gender, age, and marital status (see Table 2 in the overview paper; Cook et al., this issue).²⁵ Most participants were non-Hispanic Whites and had some college education. Most participants had moderate to severe health limitations. Study dropout was 4% for participants in the COPD and Depression groups, 16% for CHF, and 21% for Pain. Comparison of baseline characteristics between participants with and without complete data suggested some differences, indicating that missing data are not missing completely at random (MCAR).^{30,31}

Responsiveness

The results of the mixed models for the PROMIS Social Function measures are summarized in Table 1. Least squares means at baseline and follow-up are shown in Figure 1. Four of the clinical groups experienced statistically significant ($p < 0.05$) improvement in Satisfaction with Participation in Discretionary Social Activities over time, with estimated mean change scores ranging from 2.6 to 9.5. One clinical group (COPD-stable) changed very little over time.

For most participants who reported that their global or overall health changed for the better, there was a corresponding medium to large improvement in Social Function over time (standardized response means ranged from 0.43 to 0.88; see Table 2). One endpoint for one clinical group showed a smaller effect (0.19 for Social Roles among COPD-Exacerbation). Effect sizes for those who reported better overall health were nearly always larger than effect sizes for those who reported the same or worse overall health. However, many effect sizes for the latter groups were also positive, suggesting improved social function overall. Mean change scores are also shown in Table 2. Responsiveness to domain-specific (social activities) change exhibited some of the similar trends, i.e., larger improvement for those who reported better health, but improvement also for those with the same or worse health (Table 3).

DISCUSSION

PROMIS includes several measures of social function and social relationships that have undergone rigorous psychometric assessment and evolution, demonstrated strong properties, and are publically available in English and Spanish for use in research and clinical practice (www.assessmentcenter.net).^{19,35} The present study expanded validation efforts by conducting longitudinal evaluations of two PROMIS Social Function measures (Satisfaction with Participation in Social Roles and Satisfaction with Participation in Discretionary Social Activities).

Longitudinal studies with 599 people with chronic conditions (stable COPD, exacerbating COPD, CHF, back pain and depression) demonstrated the responsiveness to change of these two PROMIS Social Function CAT measures. The follow-up assessments were scheduled to represent sufficient time for the individuals to experience improvement in their health. These results provide further evidence of the PROMIS goal to enable comparability of experiences across diseases through measurement of common, generic symptoms and experiences that apply to people in a variety of contexts or with a variety of diseases.³⁶

If aspects of social health are to be included in clinical research and practice as outcomes, not just determinants, the ability of relevant measures to detect change over time must be established. Responsiveness (sensitivity to change) is emphasized within guidelines for evaluating the reliability and validity of patient-reported outcome measures.^{37,38} Ideally, a measure of social health demonstrates sensitivity to both improvements and deteriorations in status across the entire range of the sub-domain being assessed, while not evidencing variability in scores due to factors not associated with true changes in status.

In this study, all but the stable COPD sample experienced improvement in Social Function over time, as hypothesized, and most participants who reported improved overall health also reported a corresponding improvement in Social Function over time. Effect sizes for those who reported better overall health were nearly always larger than effect sizes for those who reported the same or worse overall health. However, many effect sizes for the latter groups were also positive, indicating improved Social Function. These results suggest that satisfaction with social functioning may not decline among people who view their overall health as worsened. Social function may be influenced by factors other than health status, particularly among people who experience worsening in their health.^{39,40} For example, people whose health declines may experience an improvement in family and other social support, or more closeness with loved ones, thereby increasing their satisfaction with social functioning. In addition, adaptation to worsening health might lead to a change in perspective about one's social role that is reflected in unchanged or even improved satisfaction.

Prior to initiating the COPD study, researchers agreed on predictions of large improvement for patients who were recovering from exacerbation of their COPD. For social health, these predictions were based mostly on analysis of the item content and prior research on the change in general health-related quality of life and physical function. The research team predicted a large magnitude of change for both social roles and discretionary social

activities. As reported here, small to moderate effect sizes were observed. This may be related to the acute changes associated with COPD exacerbation. Even during exacerbation, respondents may take into account their social function relative to their usual state. As expected, there was little change in social function for COPD patients enrolled and followed while stable. Also as expected, patients experienced a large improvement in social function after their heart transplant. For the Pain patient group, improvements were seen in both measures of social function.

In the area of mental health, increased emphasis on patient-centered research and practice has led to greater attention to “recovery” and factors that help produce improved functioning and quality of life. Previous clinical trials have often focused on short-term improvements in acute symptoms and clinical status. Such changes are important but may not be sufficient for patients who remain distressed by impairment in social and role functioning. Our results here for depressed outpatients are encouraging and consistent with the trend toward increased emphasis on “real-life” functioning. The PROMIS measures for social participation are brief, valid, and efficient tools for assessing social functioning and monitoring its improvement during the course of treatment.

There are some limitations to this project. All of the studies used v1.0 of the PROMIS Social Function measures. There is now a newer version (v2.0) with more items and a different domain structure. However, all of the v1.0 items are included in v2.0 Satisfaction with Social Roles and Activities, suggesting that these results can be carried forward into v2.0. (See online Appendix for details.) The measures used with the current clinical samples were not very sensitive to self-reported deterioration. This may reflect the possibility that through personal adaptation or positive change in the social milieu, satisfaction with social function does not worsen as health status declines. It is also possible that the use of a global rating of change as a meaningful anchor is flawed. Although these change measures have been used for over 20 years, there is some concern about their reliability and validity.⁴¹ Another possibility is that the PROMIS Social Function measures are not sensitive to change. There were some missing data in this study, and the analyses were conducted assuming the data were missing at random (MAR). It is not possible to test for the appropriateness of the MAR assumption compared to missing not at random (MNAR).^{30,31} The MAR assumption, conditional on the observed data, seems reasonable in this setting and is also appropriate for MCAR data.

This longitudinal study expands the body of evidence for the validity of two PROMIS social function measures by establishing that they are sensitive to clinical change/changes in health status. This suggests that they can be used in longitudinal observational and intervention research, alongside measures of physical and mental health, to provide a more comprehensive assessment of the impact of chronic disease on patients. These findings will also inform sample size estimation for studies to evaluate the impact of interventions on satisfaction with participation. In summary, the PROMIS Satisfaction with Social Participation item banks have demonstrated that they can be used as accurate measures of social function across a range of chronic medical conditions.

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What is new?

Key Findings

- PROMIS measures of Satisfaction with Social Participation demonstrate responsiveness to change in people with diverse chronic conditions.

What this adds to what was known?

- Evidence for responsiveness to change will enable social function to be included in clinical practice and comparative effectiveness research as an outcome, not just a determinant of health.

What is the implication and what should change now?

- PROMIS measures provide researchers and clinicians with the tools to accurately measure social function – an important but under-represented domain of health.
- Computer-adaptive tests and fixed-length short forms for social function are publicly available (www.assessmentcenter.net). Custom short forms can be designed and scored using PROMIS item response theory calibrations.

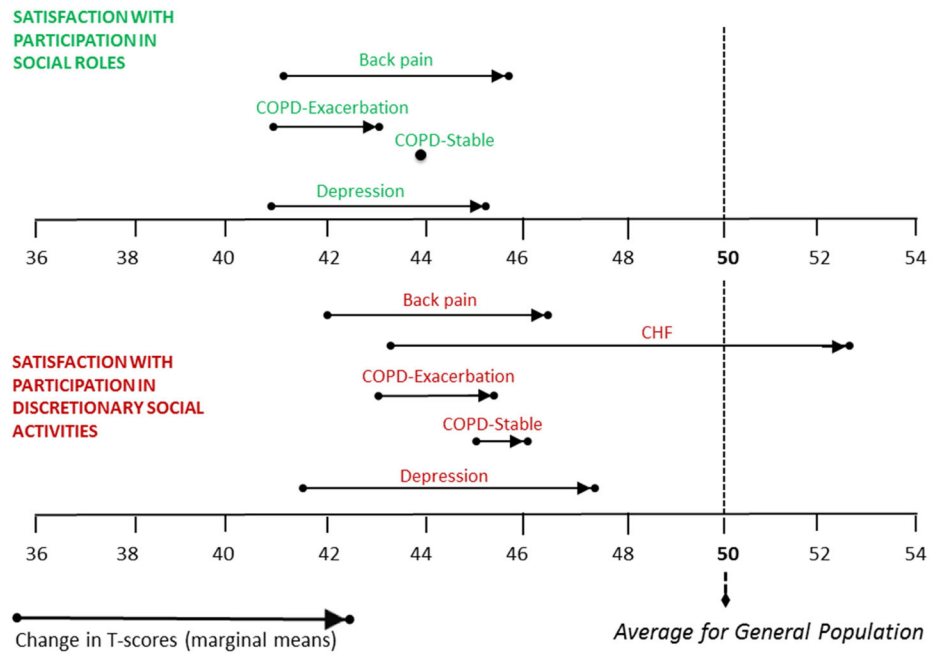


Figure 1. PROMIS Satisfaction with Social Participation in Different Clinical Groups over Time. Higher scores indicate more satisfaction with participation. A T-score of 50 reflects the mean (and 10 the standard deviation) in the US general population sample that was used to center the T-scores.⁴² *Abbreviations:* COPD, chronic obstructive pulmonary disease; CHF, chronic heart failure.

Table 1

PROMIS Satisfaction with Social Participation CAT Scores over Time

	Back Pain (n=218)	CHF (n=60)	COPD: Exacerbation (n=46)	COPD: Stable (n=79)	Depression (n=196)
Satisfaction with Participation in Social Roles					
Baseline	41.2 (40.0, 42.4)	--	41.0 (38.1, 44.0)	43.9 (41.7, 46.0)	40.8 (39.7, 42.0)
Follow-up	45.8 (44.5, 47.1)	--	43.1 (40.1, 46.1)	43.8 (41.6, 45.9)	45.2 (44.0, 46.4)
Change	4.6 (3.4, 5.8) **	--	2.1 (-0.9, 5.1)	-0.1 (-1.6, 1.4)	4.3 (3.0, 5.6) **
Satisfaction with Participation in Discretionary Activities					
Baseline	42.0 (40.9, 43.1)	43.3 (40.7, 45.9)	43.1 (40.4, 45.8)	45.1 (43.0, 47.2)	41.5 (40.4, 42.7)
Follow-up	46.2 (45.0, 47.4)	52.8 (50.0, 55.6)	45.6 (42.9, 48.4)	46.2 (44.1, 48.3)	47.4 (46.2, 48.6)
Change	4.2 (3.1, 5.3) **	9.5 (6.2, 12.8) **	2.6 (0.2, 4.9) *	1.1 (-0.3, 2.4)	5.8 (4.5, 7.1) **

Entries in the table denote the least squares mean and 95% confidence interval, as estimated in the mixed models.

Follow-up assessment was scheduled at 3 months post-baseline except for CHF (10 weeks post-transplant)

* $P < 0.05$

** $P < 0.001$

Table 2

PROMIS Satisfaction with Social Participation Responsiveness to Self-reported Change in Overall Health¹

	Back Pain (n=170)		CHF (n=46)		COPD: Exacerbation (n=34)		COPD: Stable (n=67)		Depression (n=188)	
	SRM (n)	Mean Change (SD)	SRM (n)	Mean Change (SD)	SRM (n)	Mean Change (SD)	SRM (n)	Mean Change (SD)	SRM (n)	Mean Change (SD)
Satisfaction with Participation in Social Roles										
Better overall health	0.81 (n=51)	6.3 ^{***} (7.7)	--	--	0.19 (n=7)	1.8 (9.5)	0.51 (n=13)	2.7 (5.2)	0.71 (n=43)	6.6 ^{***} (9.3)
About the same overall health	0.46 (n=95)	3.8 ^{***} (8.2)	--	--	0.32 (n=14)	3.0 (9.4)	-0.04 (n=40)	-0.3 (7.2)	0.45 (n=114)	3.9 ^{***} (8.8)
Worse overall health	0.33 (n=24)	2.5 (7.5)	--	--	0.09 (n=13)	0.7 (8.0)	-0.36 (n=14)	-1.9 (5.5)	0.27 (n=31)	2.6 (9.5)
Satisfaction with Participation in Discretionary Activities										
Better overall health	0.74 (n=51)	6.4 ^{***} (8.6)	0.83 (n=44)	9.5 ^{***} (11.5)	0.43 (n=7)	3.7 (8.5)	0.88 (n=13)	4.5 [*] (5.2)	0.74 (n=43)	7.8 ^{***} (10.5)
About the same overall health	0.55 (n=95)	3.5 ^{***} (6.3)	-- (n=0)	--	0.55 (n=14)	3.1 (5.6)	0.12 (n=40)	0.7 (5.5)	0.65 (n=114)	5.3 ^{***} (8.1)
Worse overall health	0.16 (n=24)	1.2 (7.7)	-- (n=2)	--	0.13 (n=13)	1.0 (7.5)	-0.07 (n=14)	-0.5 (6.5)	0.49 (n=31)	4.6 [*] (9.4)

¹ Participants were asked to report change in their overall health since they started the study, or since their heart transplant (for CHF participants). Only participants with data at both time points are included in this table. SRM: standardized response mean. The standardized response mean is the ratio of the mean change to the standard deviation of that change ².

-- Not measured in the study or insufficient data to report

* p<0.05

*** p 0.001

Table 3 PROMIS Satisfaction with Social Participation Responsiveness to Domain-Specific Change¹

	CHF (n=46)		COPD: Exacerbation (n=43)		COPD: Stable (n=66)	
	SRM (n)	Mean Change (SD)	SRM (n)	Mean Change (SD)	SRM (n)	Mean Change (SD)
Satisfaction with Participation in Social Roles						
Better social function/satisfaction	--		0.20 (n=10)	1.2 (6.2)	0.29 (n=9)	1.6 (5.4)
About the same social function/ satisfaction	--		0.27 (n=22)	2.6 (9.8)	-0.15 (n=36)	-1.0 (7.0)
Worse social function/satisfaction	--		0.18 (n=11)	2.2 (12.3)	0.16 (n=21)	1.0 (6.4)
Satisfaction with Participation in Discretionary Activities						
Better social function/satisfaction	0.99 (n=36)	10.9 ^{**} (10.9)	0.37 (n=10)	3.4 (9.0)	0.29 (n=9)	1.7 (5.8)
About the same social function/ satisfaction	0.13 (n=6)	1.9 (14.4)	0.56 (n=22)	3.9 [*] (7.0)	0.01 (n=36)	0.0 (4.7)
Worse social function/satisfaction	0.30 (n=4)	3.1 (10.4)	-0.06 (n=11)	-0.5 (7.3)	0.49 (n=21)	3.3 [*] (6.6)

¹ For COPD participants, change groups represent the change from baseline to follow-up in responses to the PROMIS Global question: "In general, how would you rate your satisfaction with your social activities and relationships?" For CHF participants, change groups represent responses at Time 2 to the question: "How has your ability to carry out your usual social activities and roles changed since your heart transplant?" Only participants with data at both time points are included in this table.

SRM: standardized response mean. The standardized response mean is the ratio of the mean change to the standard deviation of that change.³²

* p<0.05

** p 0.001