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## Assessing cognitive impairment using PROMIS<sup>®</sup> applied cognition-abilities scales in a medical outpatient sample

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### ABSTRACT

Having a brief, standardized, reliable, and valid self-rated test of perceived cognitive functioning could be beneficial in psychiatry clinical practice, research, and clinical trials. The PROMIS<sup>®</sup> Applied Cognition-Abilities scales were developed, evaluated, and distributed by the National Institutes of Health to measure perceived cognitive functioning. This study examines several aspects of the reliability and validity of the PROMIS<sup>®</sup> Applied Cognition-Abilities eight and four-item scales in a sample of adult and older adult medical outpatients ( $N=148$ ). Internal consistency reliability was high for both PROMIS<sup>®</sup> cognition scales. The brief four-item scale was highly correlated with the full eight-item scale ( $r_s=0.98$ ). There was a moderate correlation between the PROMIS<sup>®</sup> Applied Cognition-Abilities scales and measures of depression (PHQ-9) and anxiety (GAD-7). Subgroups of participants screening positively for depression or anxiety reported significantly worse cognitive functioning than medical controls, with large effect sizes. The base rates of individual items endorsed by depressed, anxious, and control participants are reported. More than 42% of depressed and anxious participants reported problems with their memory and concentration compared with fewer than 8% of medical controls. The field would benefit from studies using the PROMIS<sup>®</sup> Applied Cognition-Abilities scales in more demographically diverse samples and with other established measures of cognition.

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### 1. Introduction

Cognitive impairment is a cardinal feature of depressive and anxiety disorders (American Psychiatric Association, 1994, 2013; Beaudreau and O'Hara, 2008; Castaneda et al., 2008; Pedrelli et al., 2010; Nyer et al., 2013), and cognitive functioning is routinely monitored informally by psychiatrists in clinical practice. These problems contribute meaningfully to the functional impairment experienced by individuals with these disorders. For example, cognitive problems in patients with depression are associated with significant impairment in daily functioning, particularly functioning at work (Greer et al., 2010). In a study of employed outpatients with depression (Lam et al., 2012), 96% endorsed difficulty concentrating, 93% reported

problems with memory, and approximately half (52%) of the patients reported that these cognitive symptoms significantly interfered with their occupational functioning.

Having a brief, standardized, reliable, and valid self-rated test of perceived cognitive functioning could be beneficial in clinical practice, research, and clinical trials. The US National Institutes of Health have funded the development, evaluation, and distribution of the Patient-Reported Outcomes Measurement Information System (PROMIS<sup>®</sup>; Cella et al., 2007; Fries et al., 2005). One of the goals of this initiative was to develop, validate, and standardize measures of a wide variety of self-reported outcomes – across physical, psychological, and social domains – to use as common data elements for medical research. This study examines aspects of the reliability and validity of the recently released PROMIS<sup>®</sup> Applied Cognition-Abilities Short Forms 8a and 4a, two brief tests of perceived cognitive functioning. We examined the properties of these scales, including their relationships to depression and anxiety, in a sample of adult and older adult medical outpatients.

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It was hypothesized that both versions of the scale would have excellent internal consistency reliability and moderate correlations with measures of depression and anxiety.

2. Methods

2.1. Participants and procedure

Participants were 156 adult and older adult (mean age = 52.5, S.D. = 13.6) medical outpatient members of a multi-disciplinary healthcare center in British Columbia, Canada. Over half the participants were women (55.8%), married (68.6%), employed full-time (50.6%), and obtained at least a Bachelor's level education (55.1%). The majority of participants (98.7%) reported English as their dominant language. Participants completed the Patient-Health Questionnaire (PHQ-9), Generalized Anxiety Disorder scale (GAD-7), and the PROMIS® eight-item Applied Cognition-Abilities questionnaire as part of an annual medical and wellness assessment. The PROMIS® eight-item Applied Cognition-Abilities questionnaire includes all items contained in the PROMIS® four-item Applied Cognition-Abilities questionnaire, allowing the examination of both questionnaires. Approval for this study was granted by the Behavioral Research Ethics Board at the University of British Columbia.

2.2. Measures

The Patient Health Questionnaire (PHQ-9) is a nine-item self-reported screening questionnaire designed to assess and diagnose depression severity (PHQ-9; Kroenke et al., 2001). Each of the nine items corresponds to a different diagnostic criterion for major depressive disorder, as outlined in the *Diagnostic and Statistical Manual of Mental Disorders* (5th ed., text rev.; DSM-5; American Psychiatric Association, 2013). Participants rate the frequency of each symptom experienced in the last two-week period from 0 (Not at all) to 3 (Nearly every day). Depression is diagnosed if five or more of the items were endorsed at least "more than half the days" in the past two-week period. Depression severity is assessed by combining the scores for all nine items. Total scores for the PHQ-9 range from 0 to 27. Cut scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe depression, respectively. A cut score of ≥ 10 is considered optimal for detecting major depression (Kroenke, 2012) and has been frequently used in previous research. The PHQ-9 has good-to-excellent internal and test-retest reliability (Kroenke et al., 2010) in medical settings (Gilbody et al., 2007) and across ethnically diverse populations (Huang et al., 2006).

The Generalized Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006) is a seven-item self-reported questionnaire designed to assess the severity of anxiety-related symptoms over a two-week period. The seven items were derived by factor analysis of common items used in existing anxiety scales. For each item, response options range from 0 (Not at all) to 3 (Nearly every day). Responses are combined to generate a total score ranging from 0 to 21. Cut scores of 5, 10, and 15 indicate mild, moderate, and severe anxiety symptoms, respectively. A cut score of ≥ 10 has > 80% sensitivity and specificity and is considered optimal in identifying individuals with anxiety disorders (Spitzer et al., 2006; Swinson, 2006). The GAD-7 has good-to-excellent test-retest and internal reliability (Spitzer et al., 2006) and strong criterion and construct validity (Swinson, 2006; Löwe et al., 2008).

The Patient-Reported Outcomes Measurement Information System (PROMIS®) Applied Cognition-Abilities scales measure participants' subjectively-experienced cognitive functioning during the prior seven days. The PROMIS® Applied Cognition-Abilities can be administered electronically using computerized adaptive testing (CAT) or in paper-and-pencil format using the short form scales. There are three short form versions of the PROMIS® Applied Cognition-Abilities scales, composed of four, six, and eight-items, respectively. The individual items of the eight and four-item short form versions of the PROMIS® Applied Cognition-Abilities scales are outlined in Table 2. Participants rate their responses using a scale ranging from 1 (Not at all) to 5 (Very much). A total raw score ranging from 0 to 40 scores is calculated by summing participants' responses to each item. The total raw score is then converted to a T-score metric with a mean of 50, and a standard deviation fixed at 10. Higher scores indicate better perceived cognitive functioning. The normative sample used for the PROMIS® Applied Cognition-Abilities scales included individuals with chronic illnesses. Consequently, a T-score of 50 represents the average for somewhat sicker people than the general population. Because the PROMIS® Applied Cognition-Abilities eight-item scale includes all the items used in the PROMIS® Applied Cognition-Abilities four-item scale, in this study, PROMIS® Applied Cognition-Abilities four-item scores were calculated using the overlapping items from the PROMIS® Applied Cognition-Abilities eight-item scale.

3. Results

The sample as a whole reported few symptoms associated with depression (PHQ-9; M = 3.8, S.D. = 4.3) and anxiety (GAD-7;

Table 1  
Descriptive statistics for the PHQ-9, GAD-7, and PROMIS® eight and four-item Applied Cognition-Abilities scales in individuals screening positive and negative for depression and anxiety using the PHQ-9 and GAD-7 recommended cut-score (≥ 10).

Variable	Not depressed (n = 134)			Depressed (n = 14)			Inferential statistics			Not anxious (n = 130)			Anxious (n = 12)			Inferential statistics						
	M	S.D.	IQR	M	S.D.	IQR	M	S.D.	p	g	U	M	S.D.	IQR	M	S.D.	IQR	g	U	p		
PHQ-9 total score	2.79	2.71	2.0	2.65	13.0	10.0–13.3	3.58	0.00	< 0.001	2.71	2.68	2.0	0.0–5.0	10.75	4.00	10	9.0–13.0	2.87	58.00	< 0.001		
GAD-7 total score	2.00	2.36	1.0	0.62	5.28	11.0	4.0–13.5	2.78	171.50	< 0.001	1.98	2.36	1.0	0.0–4.0	13.08	2.78	13.0	10.3–14.0	4.64	0.00	< 0.001	
PROMIS 4-item applied cognition-abilities	53.44	8.22	51.4	49.7–63.8	43.75	7.55	43.6	37.8–50.6	1.19	366.00	< 0.001	53.53	8.33	53.2	49.7–63.8	43.28	9.47	42.2	35.1–49.3	1.22	306.00	< 0.001
PROMIS 8-item applied cognition-abilities	53.33	8.52	52.5	49.2–59.4	43.12	8.20	42.7	37.8–49.3	1.20	352.00	< 0.001	53.43	8.61	52.7	48.7–59.4	42.03	9.32	41.6	33.7–50.2	1.32	281.50	< 0.001

M = mean, S.D. = standard deviation, IQR = inter-quartile range, g = Hedge's g, U = Mann-Whitney U statistic.

**Table 2**Percentages and frequency (in brackets) of PROMIS<sup>®</sup> applied cognition-abilities items endorsed by medical controls, a depressed subgroup, and an anxious subgroup.

Medical controls (n=130)	Not at all	A little bit	Somewhat	Quite a bit	Very much
My mind has been as sharp as usual <sup>a</sup>	4.5 (6)	3.7 (5)	14.2 (19)	34.3 (46)	43.3 (58)
My memory has been as good as usual <sup>a</sup>	3.0 (4)	4.5 (6)	15.7 (21)	42.5 (57)	34.3 (46)
My thinking has been as fast as usual <sup>a</sup>	4.5 (6)	3.0 (4)	14.9 (20)	35.8 (48)	41.8 (56)
I have been able to keep track of what I am doing, even if I am interrupted <sup>a</sup>	4.5 (6)	3.7 (5)	16.4 (22)	33.6 (45)	41.8 (56)
I have been able to concentrate	4.5 (6)	0.7 (1)	14.9 (20)	35.1 (47)	44.8 (60)
I have been able to think clearly without extra effort	4.5 (6)	1.5 (2)	11.9 (16)	34.3 (46)	47.8 (64)
I have been able to pay attention and keep track of what I am doing without extra effort	4.5 (6)	3.0 (4)	14.9 (20)	33.6 (45)	44.0 (59)
I have been able to remember things as easily as usual without extra effort	2.2 (3)	4.5 (6)	19.4 (26)	37.3 (50)	36.6 (49)
<b>Depressed subgroup (n=14)</b>					
My mind has been as sharp as usual <sup>a</sup>	28.6 (4)	28.6 (4)	7.1 (1)	28.6 (4)	7.1 (1)
My memory has been as good as usual <sup>a</sup>	28.6 (4)	21.4 (3)	28.6 (4)	14.3 (2)	7.1 (1)
My thinking has been as fast as usual <sup>a</sup>	21.4 (3)	7.1 (1)	42.9 (6)	21.4 (3)	7.1 (1)
I have been able to keep track of what I am doing, even if I am interrupted <sup>a</sup>	7.1 (1)	21.4 (3)	35.7 (5)	21.4 (3)	14.3 (2)
I have been able to concentrate	7.1 (1)	35.7 (5)	28.6 (4)	14.3 (2)	14.3 (2)
I have been able to think clearly without extra effort	21.4 (3)	7.1 (1)	35.7 (5)	21.4 (3)	14.3 (2)
I have been able to pay attention and keep track of what I am doing without extra effort	21.4 (3)	21.4 (3)	21.4 (3)	28.6 (4)	7.1 (1)
I have been able to remember things as easily as usual without extra effort	14.3 (2)	21.4 (3)	35.7 (5)	28.6 (4)	0.0 (0)
<b>Anxious subgroup (n=12)</b>					
My mind has been as sharp as usual <sup>a</sup>	33.3 (4)	25.0 (3)	8.3 (1)	16.7 (2)	16.7 (2)
My memory has been as good as usual <sup>a</sup>	33.3 (4)	25.0 (3)	16.7 (2)	8.3 (1)	16.7 (2)
My thinking has been as fast as usual <sup>a</sup>	33.3 (4)	16.7 (2)	25.0 (3)	16.7 (2)	8.3 (1)
I have been able to keep track of what I am doing, even if I am interrupted <sup>a</sup>	8.3 (1)	33.3 (4)	25.0 (3)	25.0 (3)	8.3 (1)
I have been able to concentrate	8.3 (1)	41.7 (5)	16.7 (2)	33.3 (4)	0.0 (0)
I have been able to think clearly without extra effort	33.3 (4)	16.7 (2)	16.7 (2)	25.0 (3)	8.3 (1)
I have been able to pay attention and keep track of what I am doing without extra effort	33.3 (4)	16.7 (2)	16.7 (2)	25.0 (3)	8.3 (1)
I have been able to remember things as easily as usual without extra effort	25.0 (3)	25.0 (3)	16.7 (2)	25.0 (3)	8.3 (1)

<sup>a</sup> Items included on the four-item scale.

$M=3.0$ ,  $S.D.=4.1$ ). The sample reported slightly better perceived cognitive functioning than the normative sample used for the PROMIS<sup>®</sup> eight and four-item Applied Cognition-Abilities questionnaires ( $M=52.4$ ,  $S.D.=8.7$  and  $M=52.2$ ,  $S.D.=9.0$ , respectively, and  $M=50.0$ ,  $S.D.=10$  for the normative sample).

The internal consistency reliability of the administered instruments was examined using Cronbach's alpha. Cronbach's alpha was .82 for the PHQ-9, 0.91 for the GAD-7, 0.98 and 0.95 for the eight and four-item versions of the PROMIS<sup>®</sup> Applied Cognition-Abilities, respectively.

Analyses were conducted to examine the distribution of the PHQ-9 total scores, GAD-7 total scores, and eight and four-item PROMIS<sup>®</sup> applied cognition-abilities scales. Results from the Kolmogorov-Smirnov and Shapiro-Wilk tests for normality indicated that none of the four variables were normally distributed ( $p < 0.001$ ). Due to the non-normal distribution, Spearman's rho ( $r_s$ ) was used to examine the relationship among the GAD-7, PHQ-9, and the eight and four-item PROMIS<sup>®</sup> Applied Cognition-Abilities scales. The correlation between the eight and four-item PROMIS<sup>®</sup> Applied Cognition-Abilities scales was  $r_s=0.98$  ( $p < 0.001$ ). The PHQ-9 was significantly correlated with the GAD-7 ( $r_s=0.73$ ,  $p < 0.001$ ). The eight and four-item PROMIS<sup>®</sup> Applied Cognition-Abilities scales had similar moderate correlations with the PHQ-9 ( $r_s = -0.48$ ,  $p < 0.001$  and  $r_s = -0.46$ ,  $p < 0.001$ , respectively) and the GAD-7 ( $r_s = -0.47$ ,  $p < 0.001$  and  $r_s = -0.45$ ,  $p < 0.001$ , respectively).

Next, we examined differences in subjectively-experienced cognition using the PROMIS<sup>®</sup> Applied-Cognition-Abilities scores in clinical subgroups with depression and anxiety as well as medical controls without depression or anxiety. Using a recommended cut-score ( $\geq 10$ ) for the PHQ-9 and GAD-7 (Kroenke et al., 2010; Kroenke, 2012), 14 (9.5%) participants screened positively for depression and 12 (8.5%) participants screened positively for anxiety. Of these, nine participants (64.3% of the depressed subgroup, 75.0% of the anxious subgroup) screened positively for both depression and anxiety. The remaining 130 participants with PHQ-9 and GAD-7 scores less than 10 were used as medical controls. Independent samples  $t$ -tests revealed that

depressed and anxious participants were significantly younger ( $M=45.3$ ,  $S.D.=8.9$ ,  $t(156)=2.24$ ,  $p < 0.005$  and  $M=45.5$ ,  $S.D.=8.3$ ,  $t(150)=2.15$ ,  $p < 0.05$ , respectively) than medical controls ( $M=53.6$ ,  $S.D.=14.2$ ). No statistically significant gender differences were observed between depressed participants and medical controls,  $\chi^2(1, N=158)=0.62$ ,  $p > 0.80$ , as well as anxious participants and medical controls  $\chi^2(1, N=152)=0.11$ ,  $p > 0.74$ .

Due to unequal subgroup variances and non-normal score distributions, the significance of group differences was examined using Mann Whitney  $U$  tests. As outlined in Table 1, participants who screened positively for depression scored significantly higher than medical controls on the PHQ-9 and GAD-7, and lower on the PROMIS<sup>®</sup> Applied Cognition-Abilities eight and four-item questionnaires, with large Hedge's  $g$  effect sizes reported ( $g=3.58$ ,  $g=2.78$ ,  $g=1.19$ , and  $g=1.20$ , respectively). Similarly, participants who screened positively for anxiety scored significantly higher than medical controls on the PHQ-9 and GAD-7, and lower on the PROMIS<sup>®</sup> Applied Cognition-Abilities eight and four-item questionnaires, with large Hedge's  $g$  effect sizes reported ( $g=2.87$ ,  $g=4.64$ ,  $g=1.22$ , and  $g=1.32$ , respectively).

Lastly, because data on the PROMIS<sup>®</sup> Applied Cognition-Abilities eight and four-item scales are only starting to accumulate, we report item-level data. Specifically, the percentages of individual items endorsed by participants in the depressed, anxious, and medical control groups are reported in Table 2. Major difficulties with cognitive functioning (i.e., items rated as "Not at all" or "A little bit") were uncommon in the medical control subjects. Fewer than 10% endorsed cognitive difficulty in this range (i.e., 5.2–8.2% across items). In contrast, this degree of cognitive difficulty was endorsed by a substantial number of those with depression (i.e., 28.5–57.2%) or anxiety (i.e., 41.6–58.3%) across items.

#### 4. Discussion

This study examined aspects of the reliability and validity of the PROMIS<sup>®</sup> Applied Cognition-Abilities eight and four-item scales in



a heterogeneous sample of medical outpatients. These two cognition measures had excellent internal consistency reliability. Having internal consistency reliability at 0.95 on a four-item cognition scale is remarkable and it illustrates the careful development, using Item Response Theory, of this PROMIS<sup>®</sup> scale. A very high correlation was observed between the eight-item and four-item scales, suggesting that the short version loses little if any information compared to the long version. There were moderate negative correlations between the PHQ-9 and GAD-7 and the PROMIS<sup>®</sup> cognition measures, illustrating that higher levels of depression and anxiety are associated with worse ratings of cognition (because lower PROMIS<sup>®</sup> T scores reflect worse perceived cognition). A small percentage of the sample screened positive for depression and anxiety using the PHQ-9 and GAD-7, respectively. Compared to those who did not screen positive, those with depression or anxiety rated themselves as having much worse cognitive functioning (with effect sizes greater than 1 S.D. for both the eight and four-item scales).

Based on past clinical and research experience (GLI) using cognition rating scales with patients who have mood and anxiety disorders, it is likely that the structure of some of the PROMIS<sup>®</sup> questions will create problems for some subjects and patients. Specifically, the expression “as usual” will be problematic for some people because they will say that they do not know how to interpret the question. For example, some people with chronic depression will say that they have memory problems “for years” or “for as long as I can remember.” Therefore, asking them if their memory has been “as good as usual” over the past 7 days could result in them giving a very positive response (“quite a bit” or “very much so”) but they actually have significant subjective cognitive impairment (which they might qualify, if interviewed, by stating “my memory is terrible, but there is no difference in the past 7 days versus the past 6 months”). Similarly, this can create a problem in a clinical trial in which people are undergoing treatment for depression, they are assessed at various intervals, and they might ask what is the time frame for “as usual” (e.g., does that mean before treatment)? One possible solution to this problem would be to select items from the PROMIS<sup>®</sup> cognition item banks that do not use the expression “as usual” for a study. However, this approach would limit the use of the four-item version of the PROMIS<sup>®</sup> Applied Cognition-Abilities instrument due to three of the four questions including the “as usual” expression. Alternatively, it would also be reasonable to conduct research with patients who have mood and anxiety disorders to examine the extent to which these items actually result in problems with interpreting and responding to the questions.

This study has some limitations. The demographic characteristics of the sample used for this study limit its generalizability to other populations. First, because participants were members of a private healthcare center in Canada, they likely represent a high socioeconomic bracket (although this was not measured). Second, participants also reported an above average level of education; more than half the sample had a university degree which is considerably higher than the rate expected in the general population in Canada and the United States. Third, the study's findings are limited because ethnicity was not assessed and therefore not considered in these analyses. Because socioeconomic status and ethnicity have been associated with health behaviors and health status (Cutler and Lleras-Muney, 2006; LaVeist and Isaac, 2013), the psychometric properties of the PROMIS<sup>®</sup> cognition scales should also be compared between individuals with different educational, socioeconomic, and ethnic backgrounds in future studies.

The study is further limited by the relatively small sample of depressed and anxious participants available for analysis. Using a

small clinical sample limits the generalizability of the study to clinically similar populations. Furthermore, since most of the participants who screened positively for depression also screened positively for anxiety, the findings of this study may be limited to individuals diagnosed with both depression and anxiety. Research examining the psychometric properties of the PROMIS<sup>®</sup> Applied Cognition-Abilities instrument in depression and anxiety-only populations is therefore encouraged.

Finally, it will be important for future work to examine the relations of both the eight-item and stand-alone four-item PROMIS<sup>®</sup> Applied Cognition-Abilities scales to a comprehensive, well-validated measure of cognition. This work would help establish further establish the validity of these PROMIS scales, as well as clarify the extent to which these scales capture different domains of cognitive impairment such as executive functioning, attention, and memory.

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