

Background

- The MiCOAS project is an FDA-funded initiative which developed a set of core outcomes for use in migraine clinical trials.
- Cognitive Functioning (CF), Emotional Functioning (EF), Physical Functioning (PF), and Social Functioning (SF) measures were developed
- Previous publications detail qualitative work that identified concepts important to people living with migraine and supported item development (Mangrum et al., 2024), as well as psychometric analyses to refine and finalize measures (e.g., Houts et al., 2025)
- Current work provides evidence that 7-day recall CF, EF, PF, and SF measures produce reliable scores and show supportive evidence for use in adult migraine clinical trials
- 14-day recall versions of the CF, EF, PF, and SF measures are also available, and produced similar results

Table 1. Demographics characteristics for the full analysis set

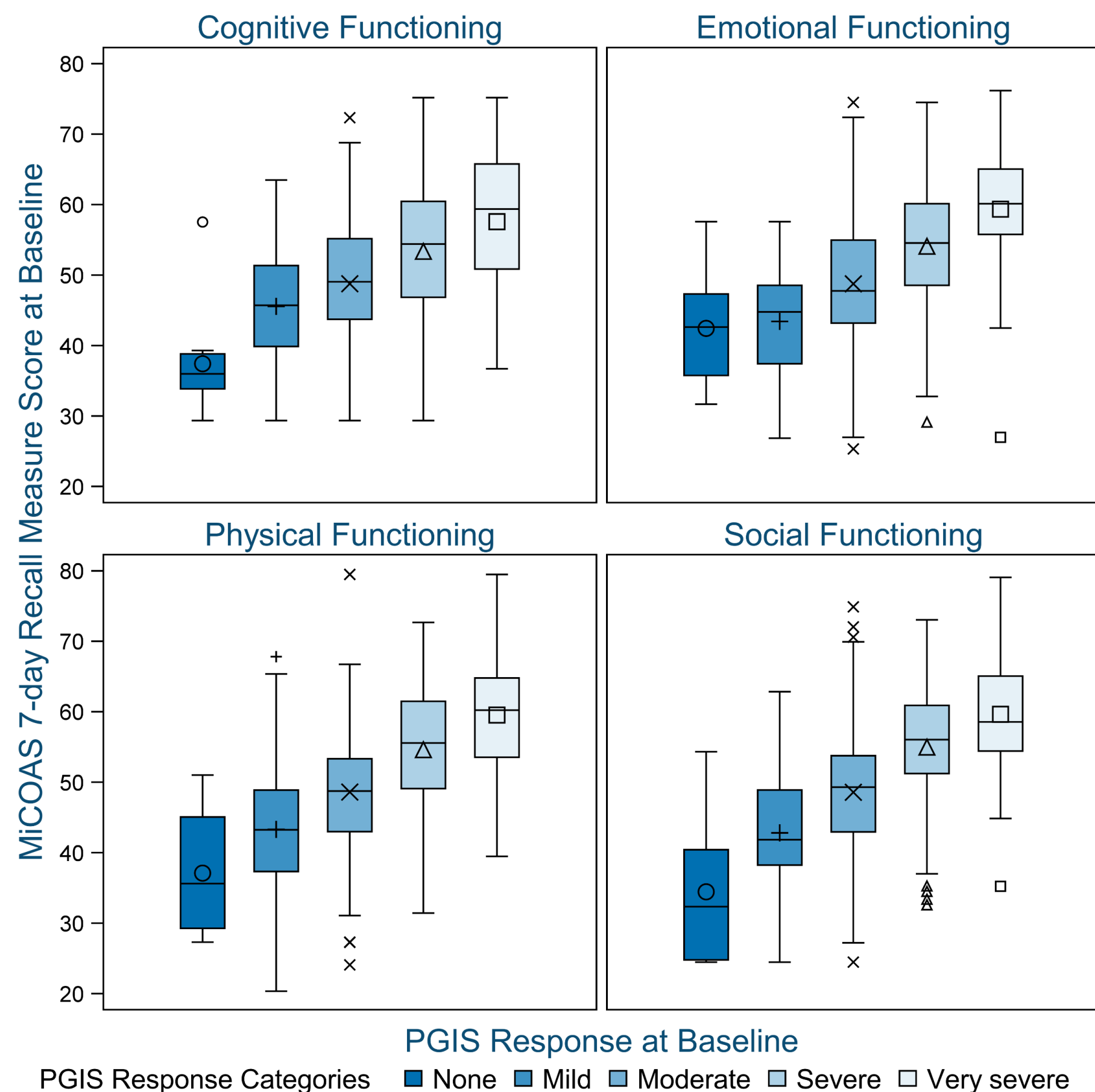
Variable	N = 611
Age (years), mean (SD)	39.06 (10.65)
MHD, mean (SD)	13.14 (6.56)
Migraine frequency group, n(%)	
Episodic	384 (62.8%)
Chronic	223 (36.5%)
Sex, n(%)	
Female	506 (82.8%)
Male	101 (16.5%)
Unknown	4 (0.7%)
Race, n(%)	
Black or African American	79 (12.9%)
White	479 (78.4%)
Other	53 (8.7%)
Ethnicity, n(%)	
Hispanic or Latino	49 (8.0%)
Not Hispanic or Latino	551 (90.2%)
Not Reported/Unknown	11 (1.8%)

Note. N= Sample size. SD= Standard deviation. Q1= First quartile, Q3= Third quartile. n= Endorsed sample size, %= Percent. MHD = Monthly headache days.

Methods

- Data from a subset of the MiCOAS observational study of US adults with self-reported migraine diagnosis were used (total N = 1155; 7-day subset n = 611)
- Cross-sectional analyses were specified *a priori* to examine the 7-day recall version of the 4 MiCOAS measures
 - For all 4 measures, higher values indicate worse function
- Reliability analyses included item response theory (IRT)-based reliability, internal consistency (coefficient alpha at Baseline), and test-retest between Baseline and Week 1 (in a stable subsample)
- Convergent and discriminant evidence was generated from correlations with reference variables
- Known-groups evidence was generated to understand how scores differ across clinically relevant groups

Figure 1. Box-and-whisker plots for MiCOAS scores across PGIS reference groups at Baseline



Results

- Of 1155 total participants, n = 611 were included in the full analysis set for the 7-day recall measures (Table 1)
- IRT-based reliability (marginal/distributional) was high:
 - CF = 0.91; EF = 0.88; PF = 0.93; SF = 0.93
- Internal consistency (Cronbach's alpha) was high:
 - CF = 0.90; EF = 0.84; PF = 0.91; SF = 0.92
- Test-retest reliability (ICC value) was adequate:
 - PGIS defined stable subsample between Baseline and Week 1
 - CF = 0.70; EF = 0.84; PF = 0.69; SF = 0.67
- Correlations with reference variables met or exceeded most magnitude and met all directional expectations (Table 2)
- Known-groups analyses show mean MiCOAS scores increase with more severe PGIS responses, as expected (Figure 1)
- Overall, scores performed generally as expected in an observational study dataset

Table 2. Correlations between MiCOAS scores and reference measures at Baseline

Variable	CF		EF		PF		SF	
	Expectations	r	Expectations	r	Expectations	r	Expectations	r
Age (years)	0.0 to 0.3	-0.08	0.0 to 0.3	-0.13	-0.2 to 0.2	-0.08	0.0 to 0.3	-0.05
HIT-6 Total (4-week recall)	0.1 to 0.4	0.45	0.0 to 0.3	0.58	0.4+	0.53	0.0 to 0.3	0.58
MSQ v2.1 (4-week recall)								
Role Function-restrictive	-0.3 to 0.0	-0.58	-0.5 to -0.3	-0.63	-0.5 to -0.3	-0.64	-0.5 to -0.3	-0.68
Role Function-preventive	-0.3 to 0.0	-0.56	-0.5 to -0.3	-0.56	-0.5 to -0.3	-0.64	-0.5 to -0.3	-0.70
Emotional Function	-0.3 to 0.0	-0.45	-0.5+	-0.65	-0.3 to 0.0	-0.48	-0.5 to -0.3	-0.57
MFIQ v2 (7-day recall)								
Physical Function	0.0 to 0.3	0.51	0.1 to 0.4	0.51	0.3 to 0.8	0.62	0.1 to 0.4	0.64
Usual Activities	0.0 to 0.3	0.66	0.1 to 0.4	0.61	0.4+	0.74	0.1 to 0.4	0.79
Social Function	0.0 to 0.3	0.55	0.4+	0.55	0.1 to 0.4	0.65	0.4+	0.74
Emotional Function	0.0 to 0.3	0.46	0.3 to 0.8	0.70	0.0 to 0.3	0.54	0.3 to 0.8	0.64
MOS-Cog-R (7-day recall)	-0.5+	-0.80	-0.3 to 0.0	-0.55	-0.3 to 0.0	-0.56	-0.3 to 0.0	-0.57

Notes. CF = Cognitive functioning. EF = Emotional functioning. PF = Physical functioning. SF = Social functioning. HIT-6 = 6-item Headache Impact Test. MSQ = Migraine-specific Quality of Life Questionnaire. MFIQ = Migraine Functional Impact Questionnaire. MOS-Cog-R = Revised MOS Cognitive Function.

Summary

- ❑ New patient-centered MiCOAS 7-day recall-based measures assessing CF, PF, EF, and SF were found to be appropriate for use in migraine clinical trials

Conclusions

- ✓ 4 patient-centered MiCOAS measures produced evidence supporting their use in adult migraine clinical trials
- ✓ All 4 measures generate reliable scores
- ✓ All 4 measures behaved as expected in cross-sectional correlation and known-groups analyses
- ✓ Future work will examine longitudinal properties in clinical trials and meaningful score differences

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