The Migraine Clinical Outcome Assessment System (MiCOAS) measures: Physical Functioning

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Background

- The Migraine Clinical Outcome Assessment System (MiCOAS) project is a multi-year, FDA-grant supported program to establish a core set of outcomes for use in migraine clinical trials
- A 9-item physical functioning (PF) domain was developed as part of the MiCOAS recall-based measures
- The 7- and 14-day recall-based measures for PF are presented here along with scale development results

Methods

- Extensive qualitative work with people living with migraine led to the development of candidate PF items
  - PF item responses ranged from 1=Never to 5=Always
- A 3-cohort observational study collected data on the draft MiCOAS measures
  - Participants met the study migraine case definition
- Item-level analyses, polychoric correlations, categorical confirmatory factor analyses, and item response theory (IRT) analyses (including differential item functioning [DIF])
- Quantitative and qualitative results were used to inform the final version of the MiCOAS PF measure

Table 1. Demographic characteristics for the full analysis set

	(N=1155)
Age (years), mean (SD)	38.86 (10.82)
Sex, n(%)	
Female	940 (81.4%)
Male	209 (18.1%)
Unknown	6 (0.5%)
Race, n (%)	
Black or African American	162 (14.0%)
White	896 (77.6%)
Other	97 (8.4%)
Ethnicity, n (%)	
Hispanic or Latino	105 (9.1%)
Not Hispanic or Latino	1036 (89.7%)
Not Reported/Unknown	14 (1.2%)
MHD, mean (SD) (N = 1149)	13.06 (6.65)

Notes. N= Sample size. SD= Standard deviation. n= Endorsed sample size, %= Percent. MHD - Monthly Headache Days.

Results

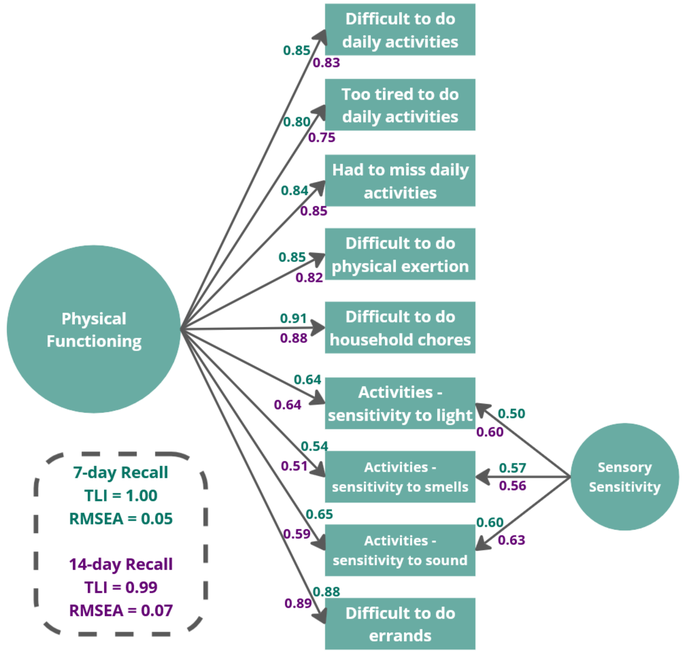
- The 1155 participant sample was predominantly female (81.4%), white (77.6%) and of middle age (mean = 38.9 years, range = 18-75 years) (Table 1)
- No issues with missingness or floor/ceiling effects were present in the item-level descriptives and frequency tables (Table 2)

Table 2. Item frequencies at Baseline for 7-day recall PF measure

Item content	n	Never	Rarely	Sometimes	Very often	Always
Difficult to do daily activities	605	6 (1.0%)	87 (14.4%)	328 (54.2%)	160 (26.4%)	24 (4.0%)
Too tired to do daily activities	605	14 (2.3%)	90 (14.9%)	257 (42.5%)	213 (35.2%)	31 (5.1%)
Had to miss daily activities	605	48 (7.9%)	144 (23.8%)	277 (45.8%)	120 (19.8%)	16 (2.6%)
Difficult to do physical exertion	602	61 (10.1%)	110 (18.3%)	236 (39.2%)	160 (26.6%)	35 (5.8%)
Difficult to do household chores	605	32 (5.3%)	125 (20.7%)	262 (43.3%)	147 (24.3%)	39 (6.4%)
Activities - sensitivity to light	605	47 (7.8%)	116 (19.2%)	255 (42.1%)	159 (26.3%)	28 (4.6%)
Activities - sensitivity to smells	606	104 (17.2%)	167 (27.6%)	206 (34.0%)	111 (18.3%)	18 (3.0%)
Activities - sensitivity to sound	604	55 (9.1%)	124 (20.5%)	254 (42.1%)	144 (23.8%)	27 (4.5%)
Difficult to do errands	606	37 (6.1%)	113 (18.6%)	273 (45.0%)	150 (24.8%)	33 (5.4%)

- Investigating polychoric interitem correlations showed moderate-to-strong association among the 9 candidate items (mean[min, max] correlation 7-day: 0.59 [0.40, 0.78]; 14-day: 0.55 [0.32, 0.74)
- Internal consistency was adequate across both the 7- and 14-day recall PF measures (coefficient alpha estimate of 0.91 [7-day] and 0.89 [14-day])
- IRT test reliability function showed comparable and adequate reliability (>0.70) across wide range of standardized PF scores for both 7- and 14-day recall periods

Figure 1. Path diagram with standardized factor loading and model fit estimates for 7- and 14-day recall PF measures



- Factor analyses and multidimensional IRT model results showed comparable factor loadings and good model fit to the item responses across the 7- and 14-day recall periods (Figure 1)
  - An additional factor was necessary to model relationship between items covering sensitivity to light, smells, and sound (right-hand side of Figure 1)
- No meaningful DIF was found across episodic and chronic migraine groups or recall period

Summary

❑ MiCOAS 7- and 14-day recall-based measures assessing PF in migraine were developed and showed strong psychometric properties

Conclusions

- ✓ Results across the MiCOAS 7- and 14-day PF measures were similar
- ✓ The PF measures showed strong psychometric properties including good model fit and moderate-to-strong interitem correlations and factor loadings
- ✓ Internal consistency and high reliability across a broad range of PF was observed
- ✓ Future work is underway to evaluate evidence of validity for the MiCOAS PF measures

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