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

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Background

- Impairment of cognitive functioning (CF) before, during, and after the headache phase is an extremely important impact in migraine (Gerstein et al., 2023; Gil-Gouveia et al., 2015)
- However, CF is not often assessed in preventive migraine clinical trials (McGinley et al., 2021)
- For this reason, a target of the MiCOAS project was the development of a recall-based measure of self-reported CF

Methods

- Ten candidate CF items were developed based on qualitative work with people living with migraine
  - CF item response options ranged from either 1=Never to 5=Always or 1=Not difficult at all to 5=Unable to do
- A large, 3 cohort, observational study collected data on draft MiCOAS measures and other relevant measures (Table 1)
  - Participants met the study migraine case definition
- Completed item-level, polychoric correlation, categorical confirmatory factor, and item response theory (IRT) analyses

Table 1. Demographics characteristics for the full analysis set

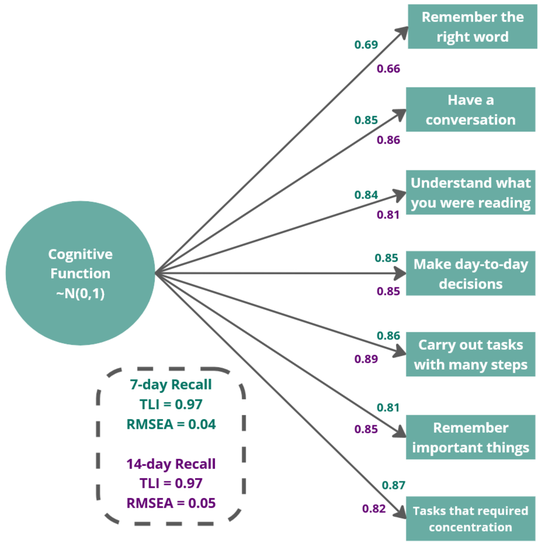
	(N=1155)
Age (years), mean (SD)	38.86 (10.82)
Sex, n(%)	
Female	940 (81.4%)
Male	209 (18.1%)
Unknown	6 (0.5%)
Race, n (%)	
Black or African American	162 (14.0%)
White	896 (77.6%)
Other	97 (8.4%)
Ethnicity, n (%)	
Hispanic or Latino	105 (9.1%)
Not Hispanic or Latino	1036 (89.7%)
Not Reported/Unknown	14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

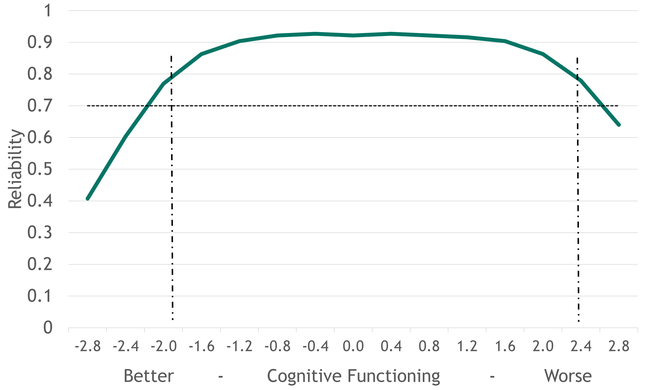
- A total of 1155 participants were included in the full analysis set (Table 1)
- Review of the item response frequencies showed severe response options were rarely used and possible floor effects for 2 7-day CF items and 1 14-day CF item
- Polychoric interitem correlations showed moderate-to-strong associations among the 10 candidate items (average[min, max] correlation 7-day: .62 [.48, .79]; 14-day: .60 [.44, .78])
- Based on initial quantitative criteria and discussions with multiple stakeholders, 3 candidate items were dropped
  - 7 CF items retained for psychometric analyses

Figure 1. Path diagram with standardized factor loadings



- 7-day and 14-day factor loadings were moderate-to-strong and similar in magnitude (Figure 1)
- IRT model results also showed good model and item-level fit across the 7- and 14-day recall periods (Figure 1)
- IRT-based reliability was acceptable for a large range of CF (Figure 2)
- Differential item functioning analyses suggested that measurement properties were similar across 7- vs. 14-day recalls and for individuals with episodic vs. chronic migraine

Figure 2. IRT-based reliability for 7-day CF measures



Notes. Black horizontal dashed line denotes reliability = 0.70, a typically used minimum for acceptable reliability. Black vertical dashed lines indicate limits of measurement (i.e., lowest and highest possible score that can be obtained from the item set).

- Internal consistency was also found to be high for both the 7- and 14-day recall CF measures (coefficient alpha estimate of 0.90 for both)

Summary

❑ Following regulatory recommendations for patient-focused scale development and psychometric best practices, MiCOAS 7- and 14-day recall-based measures assessing CF were developed

Conclusions

- ✓ Candidate CF item set was reduced from 10 to 7 items
- ✓ IRT and factor analysis showed good model and item fit and strong factor loadings
- ✓ Internal consistency and reliability were excellent
- ✓ Similar results for 7-day and 14-day recall CF measures
- ✓ Future analyses will generate validity evidence to support the MiCOAS CF measures

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