

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
- Previous research shows that emotional functioning (EF) is important to patients, but is rarely assessed in acute or preventive migraine clinical trials (McGinley et al., 2021)
- The current work presents the final 7- and 14-day recall-based measures for emotional functioning, along with development and initial validation investigation results from the MiCOAS quantitative study

Methods

- Candidate items for the EF scale were developed after extensive qualitative work with people living with migraine
 - EF item responses ranged from 1=Never to 5=Always
- A large, 3 cohort, observational study collected data on the draft MiCOAS measures and other relevant headache- and migraine-specific measures (Table 1)
 - Participants met the study migraine case definition
- Completed item-level, polychoric correlation, categorical confirmatory factor, item response theory (IRT), and reliability analyses
- Along with qualitative information (e.g., content importance to people with migraine), quantitative results were used to select candidate items for the final versions of the MiCOAS EF measures

Table 1. Diary lengths and recall periods for cohorts

	Daily Diary	Retrospective Recall MiCOAS
Cohort 1 (n = 169)	56 days	14-day
Cohort 2 (n = 375)	28 days	14-day
Cohort 3 (n = 611)	28 days	7-day

Results

- A total of 1155 participants were included in the full analysis set (Table 2)

Table 2. 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.

- No issues with missingness or floor/ceiling effects were present in the item-level descriptives and frequency tables
- Investigating polychoric interitem correlations showed moderate-to-strong association among the 6 candidate items (average[min, max] correlation 7-day: .52[.30, .70]; 14-day: .50[.36, .70])
- Multidimensional IRT model results showed good model fit to the item responses across the 7- and 14-day recall periods (Table 3; TLI = 0.97, RMSEA = 0.04-0.05)
- Both factor analyses showed similarly strong general factor loadings across 7- and 14-day recall measures (average[min, max] loading 7-day: .72[.53, .89]; 14-day: .72[.54, .92])
- Internal consistency was also found to be adequate across both the 7- and 14-day recall EF measures (coefficient alpha estimate of 0.84 [7-day] and 0.83 [14-day])

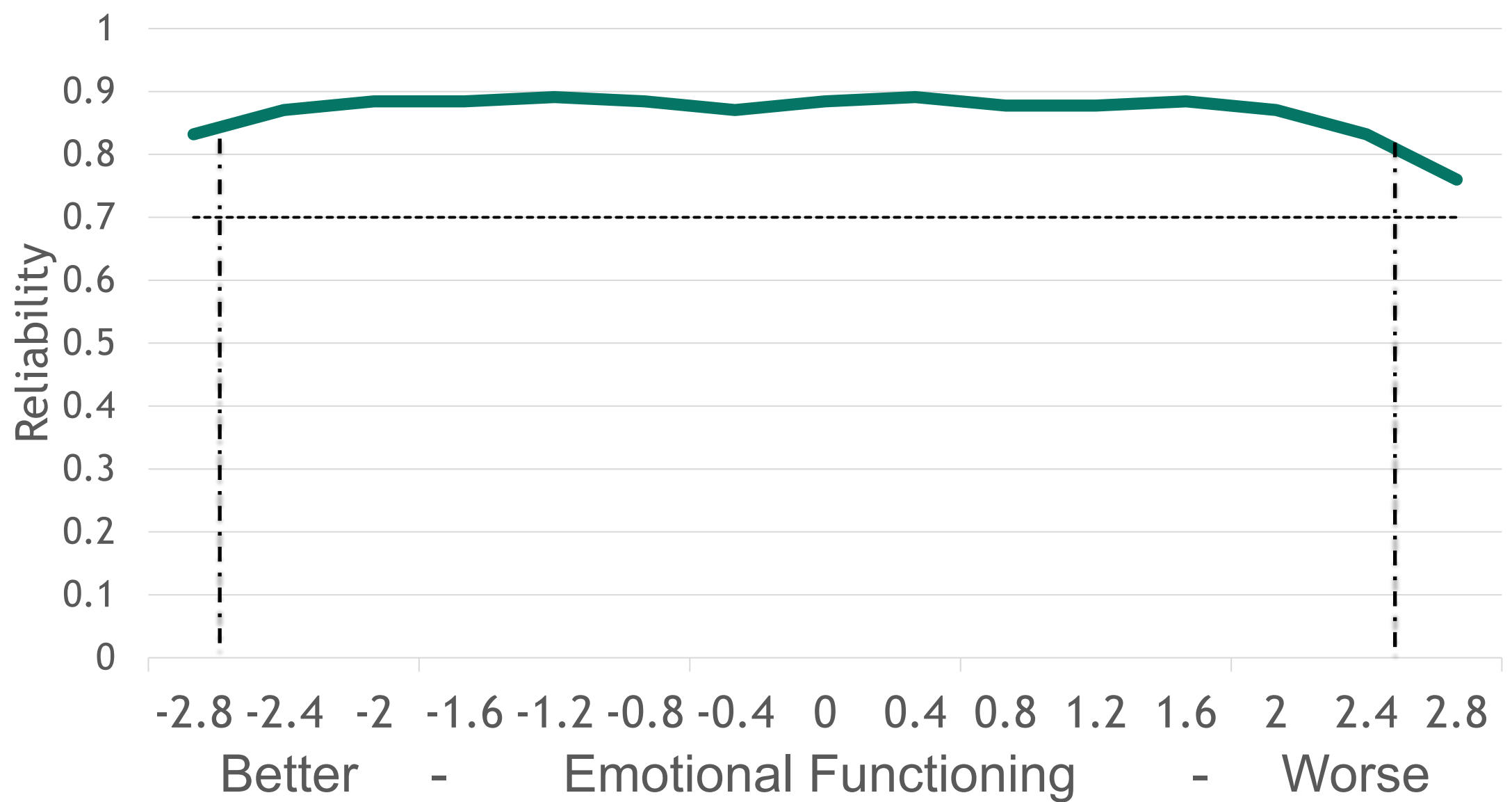
Table 3. Standardized factor analysis loading estimates

Item content	7-day loading	14-day loading
Not have control of life	0.74	0.71
Worried about migraine attack	0.56	0.61
Concern that migraine attacks affect other people's lives	0.53	0.54
Sad or depressed	0.82	0.76
Frustrated	0.89	0.92
Irritable	0.78	0.75
Model Fit	TLI	0.97
	RMSEA	0.04
		0.05

Note: A second method factor accounting for local dependence between 'Worried about a migraine attack' and 'Concern that migraine attacks affect other people's lives' is not presented here.

- IRT-based reliability was acceptable from -2.8 standard deviations below the mean to 2.4 standard deviation above the mean (Figure 1)

Figure 1. IRT-based reliability for 7-day EF measures



- Differential item functioning analyses suggested that measurement properties were similar across 7- vs. 14-day recalls and for individuals with episodic vs. chronic migraine

Summary

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

Conclusions

- ✓ Results across the MiCOAS 7- and 14-day EF measures were similar
- ✓ The EF 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 EF was observed
- ✓ Future analyses will generate validity evidence to support the MiCOAS EF measures

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