

# Derivation and Validation of a Weighted Composite Engagement Index (WCEI) to Link Digital Therapeutic Engagement with Clinical Outcomes in Episodic Migraine

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- Digital therapeutics (DTx) capture continuous usage data that objectively quantify patient engagement with the treatment, and are often analyzed and presented in isolation from clinical endpoints
- Composite scores have been proposed as a way to combine engagement metrics into a single score that may have more utility in clinical research trials
- This exploratory analysis attempted to use elastic net penalized regression to select from multiple engagement metrics and combine them into a single composite index that could be applied to an independent dataset
- The analysis was conducted on CT-132, a novel DTx for preventive treatment of episodic migraine (EM) that has demonstrated clinical effectiveness and high engagement

## What We Did

Data included mITT participants in the active treatment arm from two RCTs evaluating CT-132 in patients with EM

Elastic net applied to first RCT dataset (n=278)

Coefficient weights for predictors extracted from model

Weights applied to second RCT dataset to compute a standardized composite index (n=54)

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## What Was Found

- Limited data variability due to high engagement success prevented a full methodological exploration of the elastic net and WCEI models.
- For elastic net, the best fitting model retained all overall and modality specific engagement variables ( $\alpha = 0.2$ ). The lack of variance restricted the models ability to identify predictive patterns.
- A standardized, composite engagement score - the WCEI - was calculated based on the initial model and applied to the bridging study dataset. Again, low variability in the key variables reduced interpretation of the model.
- The results illustrate the challenges with developing a standardized composite score that can be applied across datasets and products.

## Additional Findings

A linear regression provided additional insight into the relationship between overall engagement and clinical outcomes. Importantly, the completion of therapeutic elements was associated with reduced MMD, whereas the number of app opens was not.

	$\beta$	Std. Error	t-value	p-value
<i>Intercept</i>	-8.72	1.03	-8.46	0.00
Daily eDiary	0.09	0.02	4.04	0.00***
Daily Treatment Elements	-0.02	0.02	-1.45	0.15
Daily App Opens	0.00	0.00	0.23	0.82

### Distribution of Engagement: Daily Treatment Elements

Engagement was high, with the majority of the sample completing therapeutic elements daily throughout the treatment

