

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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Methodological Issue Being Addressed Currently engagement data from medical devices, such as digital therapeutics, are a rich data source that is underutilized and inconsistently reported. Largely, engagement metrics are considered in isolation, failing to integrate and prioritize data that index clinical outcomes. This is particularly problematic in early phase studies when it is critical to isolate therapeutic potential. A standardized, multidimensional measure of engagement can synthesize clinically-relevant engagement metrics, and may accelerate clinical development by increasing confidence in smaller, early phase study results.

Introduction Digital therapeutics (DTx) capture a steady flow of objective usage data that can serve as a window into patient behavior. This work addresses the current methodological gap by shifting from reliance on simple, unweighted metrics (e.g., total app opens) that fail to differentiate between passively opening the app and actively engaging with the content, to psychometrically robust, multidimensional composite scores that are associated with clinical outcomes. The proposed work builds on current frameworks of composite indices that have not been fully defined or empirically derived for engagement^{1,2}. The analysis leverages high-frequency digitally-derived behavioral data from a randomized controlled trial of a DTx to develop a Weighted Composite Engagement Index (WCEI) that quantifies the relationship between engagement and clinical improvement. The WCEI is replicated in a second, smaller sample to explore how a composite score can validate results of early stage discovery research and increase the probability of clinical and regulatory success before testing in a larger, controlled trial.

Methods Data from a 12-week randomized controlled trial of a DTx for the treatment of episodic migraine (NCT05853900) will be analyzed. Multiple engagement metrics will be integrated to develop the WCEI, including general interactions (app opens, duration of sessions, lesson completion) and engagement in specific therapeutic components. The clinical outcome will be the change from baseline in the primary effectiveness endpoint, Monthly Migraine Days (MMDs). To derive objective weights for the WCEI, a Least Absolute Shrinkage and Selection Operator (LASSO) penalized linear regression model will be employed, using the individual usage metrics as predictors and MMDs as the dependent variable. The resultant non-zero regression coefficients will be standardized and used as weights in the WCEI. The WCEI will then be validated in a Phase 3 bridging study of the same DTx.

Results A total of 278 participants are projected to be included in the analysis. The central hypothesis is that the composite index will predict the clinical outcome (MMDs) more strongly than any individual metric. We expect to replicate the composite index in an independent secondary sample of approximately 54 participants completing the same DTx for episodic migraine.

Conclusion The proposed WCEI derivation represents a methodologically robust approach to identifying engagement metrics that predict reduction in MMD – a step towards defining engagement by the interactions that result in clinical improvement. This scalable methodology not only enhances the interpretability of a migraine DTx asset, but also provides a framework to standardize engagement measurement across the digital therapeutics field and use small samples for rapid initial clinical validation.

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Keywords

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digital therapeutics

migraine

engagement

Guidelines I have read and understand the Poster Guidelines

Disclosures The authors thank the trial participants and the study investigators for their contributions to the ReMMi-D and ReMMi-C studies. We acknowledge the many contributions of the team involved in the technical and clinical development process. This study was funded by Click Therapeutics, Inc. At the time of study, Julia Longenecker, Olya Besedina, Karina Palafox, Cassandra Snipes, and Laura Taraboanta were all employees at Click Therapeutics, Inc. Jacqueline Lutz was a consultant to Click Therapeutics at the time of study. The authors report no conflicts of interest for this work.