Longitudinal convergence of dispersed clinical ratings and ecological momentary assessment burst assessments of negative symptoms in schizophrenia

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What is the Methodological Issue Being Addressed? Traditional clinical trials for negative symptoms involve dispersed in-person assessments which, in longer trials, can occur several months apart, posing a substantial recall burden. The ecological momentary assessment (EMA) method has the potential to capture rich in-the-moment reports of emotions and experiences related to negative symptoms while minimizing recall demands. In the context of a 12-month open label trial, this convergent validity study evaluated the relation between monthly burst EMA assessments and interspersed in-person clinical ratings of negative symptoms.

Introduction We evaluated whether EMA surveys assessing behavioral indicators of reduced experiential negative symptoms predicted subsequent clinical ratings on the Negative Symptoms Assessment (NSA). To evaluate the potential impact of attrition, we separately examined EMA predictors of the first post-baseline NSA assessment and the final NSA assessment available for each participant.

Methods During a 12-month open label study of KarXT in schizophrenia, the NSA was administered approximately every 4 months for up to one year. Participants completed EMA surveys 3 times per day, 7 days per week, one week per month, for up to a year. Hierarchical linear modeling (HLM) whether EMA variables predicted subsequent NSA scores at early (month 4) and later (last available) time points. Proportions of EMA surveys answered at home, alone, and while engaging in passive or unproductive activities, as well as concurrent momentary positive affect (PA: Happy and relaxed) intensity were predictors. Time since baseline defined the repeated-measures factor and baseline NSA was included as a covariate in the HLMs.

Results From a total of 450 enrolled patients, 75% completed a month 4 NSA assessment and 12-month completion rates were slightly above 50%. 12,636 EMA surveys were completed by participants prior to their month 4 NSA analyses and 25,548 surveys were completed by the participants' final NSA assessment. Across the overall 12-month study period, there were significant effects for time since baseline, with both NSA ratings and EMA variables improving over time. During the first 4 months of EMA data collection, significant time effects indicated decreases in surveys answered when home [p=.003] or alone [p=.004], more productive [p<.001] and fewer passive activities [p=.009], and higher PA [p<.001] compared to baseline. The improvements on these EMA variables jointly predicted lower month 4 NSA ratings, $X^2(35)=5056.79$, $p<0001$; each predictor was independently significant [all p<.001]. Similarly, analyses on the final NSA available

for each participant indicated that improvements on the same EMA variables predicted NSA ratings both jointly X2 (60)=9862.24, p<00001, and individually [p<.001].

Conclusion NSA ratings and EMA indices of experiential negative symptoms both improved during a 12-month open label trial. Further, the EMA indicators significantly predicted subsequent NSA scores across early and late phases of the trial, suggesting that EMA-related changes are meaningfully related to NSA changes detected by clinical raters. These findings support the validity of EMA as negative symptom assessment method that minimizes burdens associated with recall and with in-person clinical assessments.

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Keywords

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