Title: Development and Validation of a patient-reported outcomes symptom measure (ePRO) for assessing Awareness of Insight in Schizophrenia: **Preliminary Findings**

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Methodological Question:

Interest in the self-perception of individuals with schizophrenia is increasing because of the gap between the physician and patient's perceptions of symptoms and the technological resources to gather ecologically valid information from community-dwelling patients. Clinical trials for schizophrenia are increasingly using electronic methods to collect patient-reported outcomes (ePRO). Hence, several ePROs have been developed to better understand patients' experience with their own illness. Lack of insight into illness is a core feature of schizophrenia that is multidimensional, and related to poor compliance with treatment. Assessing insight into illness via an ePRO, and attaining patient perception may provide information to the clinician at a more reliable rate as data is collected in real-time to facilitate functional and risk assessment. Core questions are whether it is feasible for patients with schizophrenia to complete an ePRO on their smartphone, and will the results obtained from patient's perception of insight compare to clinician assessed insight, and passive digital biomarkers of psychiatric morbidity.

Aims:

The aim is to (1) develop a short, multidimensional self-report measure of insight (Awareness of Insight Scale, AIS), (2) assess validity and reliability, and (3) evaluate feasibility in schizophrenia study context.

Methods:

A Delphi method was used to facilitate expert participation and ensure face and content validity for development of the AIS. The SUMD and SCI-PANSS G12 Lack of Insight were used as a reference for scale development. A new scale with 8 items incorporating David's (1990) dimensions of insight was developed consisting of: (1) awareness of having a mental illness, 2) relabel unusual mental events as pathological, and 3) adherence to treatment. The scale was presented as a smartphone app for 6 months via a parent study assessing passive digital biomarkers of psychiatric morbidity (Mindstrong Health). Internal consistency, test-retest reliability and validity were assessed by comparing with PANSS: G12 and Disorganization Factor in a sample of 16 outpatients. The ePRO was designed with push messages suggesting patients complete the scale once per week.

Results:

The 8 items selected for inclusion in the AIS assessed awareness of psychiatric illness, need to take medications, attributing being sad or upset to unusual experiences, and belief that s/he is always correct. Of the 16 subjects enrolled, data is presented for 10 subjects, as the remaining 6 subjects were missing or arrested. Of the 10 subjects, all completed at least 2 weeks of AIS assessments on their smartphone with 60% completing all weekly assessments since enrollment with an average of 4.10 minutes to complete. Internal Consistency was high ($\alpha = 0.79$). Preliminary findings show scores on AIS correlated with PANSS G12 ($r = 0.43$, $p < 0.05$) and with the PANSS Disorganization Factor ($r = 0.38$, $p < 0.05$). Test-retest reliability are moderate with ICCs = 0.70.

Conclusion:

Preliminary findings show the AIS is a short, reliable and valid measure of insight in schizophrenia. Expert consensus ensures its face and content validity. Findings support its feasibility in a small sample of outpatients with chronic schizophrenia; additional sample size is needed to confirm patient acceptability, reliability and validity.