

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 symptom, and the technological resources to gather information more frequently and ecologically more valid 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 devices with electronic reminders, 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 of the study is to

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

METHODS

Scale Development

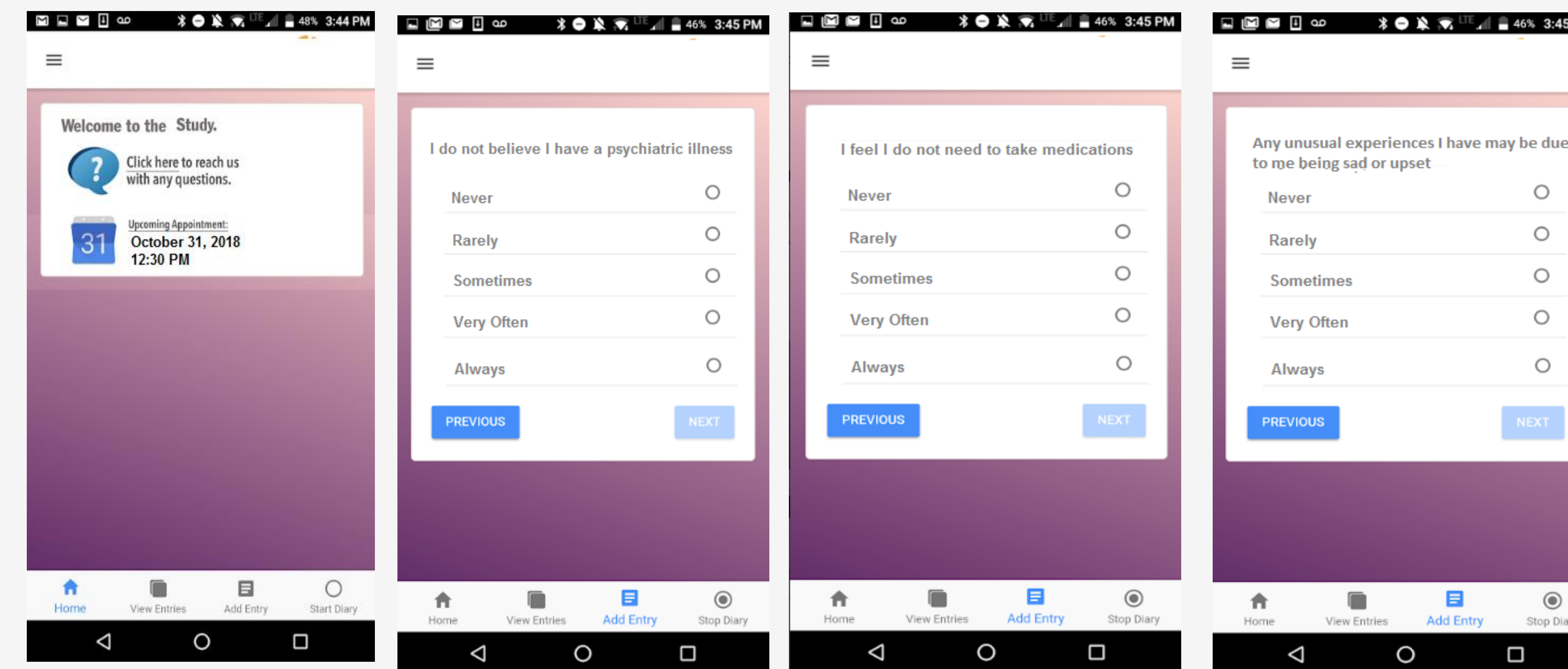
- A Delphi method was used to facilitate expert participation and ensure face and content validity for development of the AIS. The SUMD and SCI-PANSS G12 Lack of Insight were used as a reference in the scale development.
- A new scale with 8 items incorporating David's (1990) dimensions of insight was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

Statistical Analysis

Internal consistency, test-retest reliability and validity by comparing with rater assessed insight measures (PANSS G12, Disorganized factor) were assessed in a sample of 26 outpatients with schizophrenia or schizoaffective disorder (age 18 – 55) recently discharged from an inpatient psychiatric center and followed in the community. A confirmatory structural model was completed to assess the relationship between the AIS items and PANSS items and factors

ePRO IMPLEMENTATION

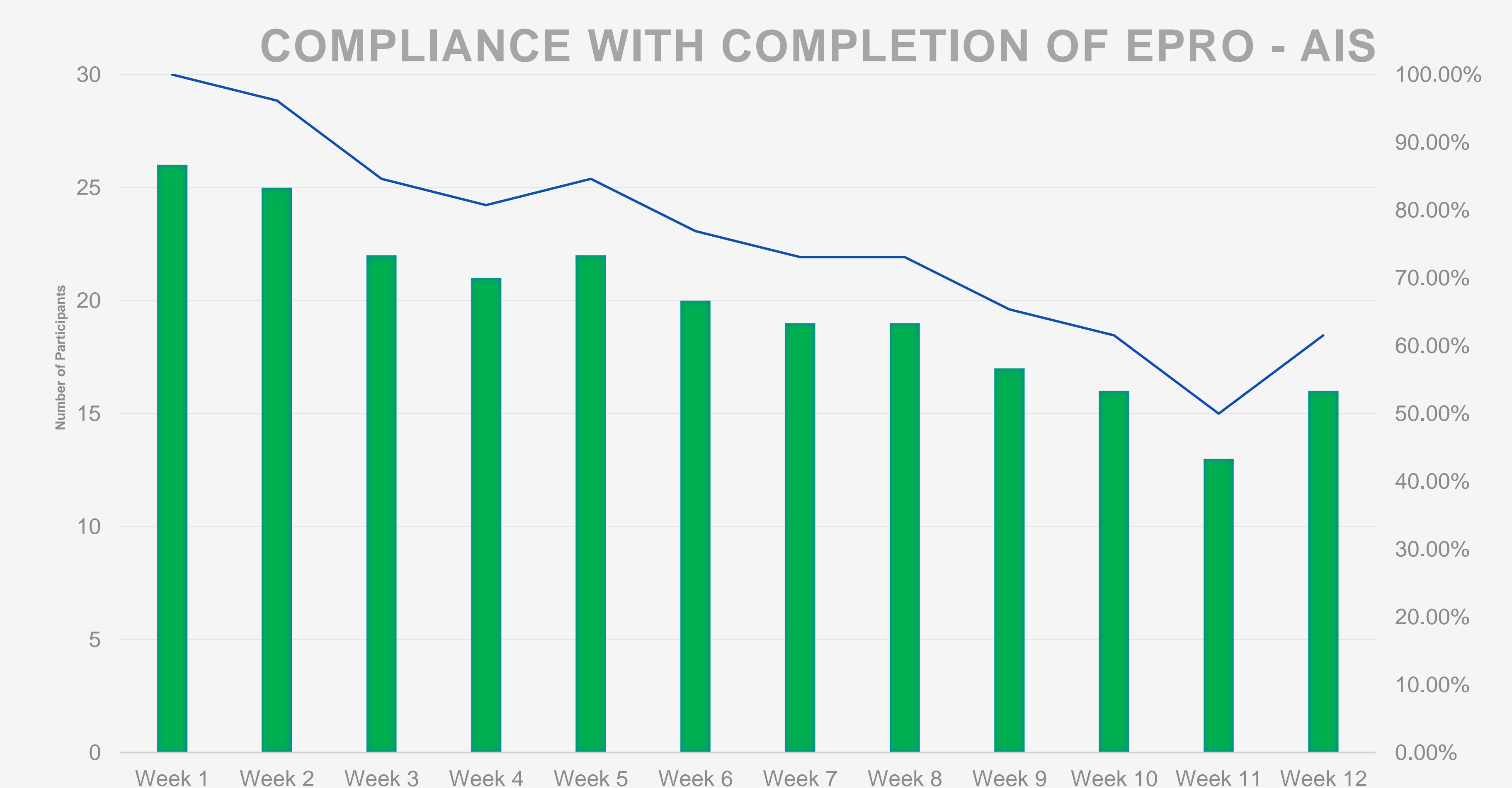
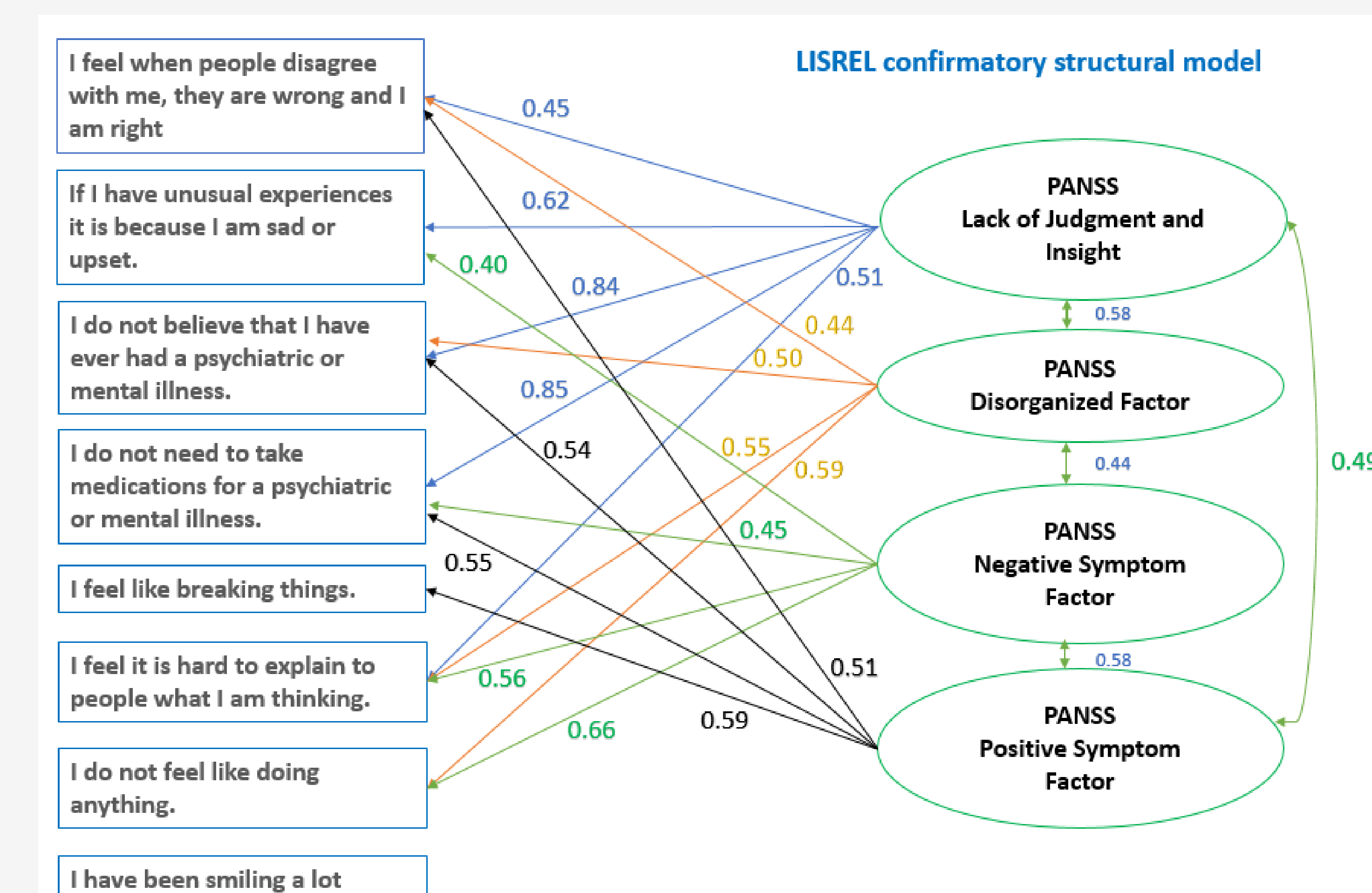
The data presented in part of a larger study assessing digital phenotyping in schizophrenia to assess early warning signs for relapse. The Awareness of Illness Scale (AIS) contains 8 items that assesses insight. Information on the screen is minimized to avoid distractions or mistakes. The AIS is deployed on the patient's phone through a secure network and data is available in real time.



Demographics	Mean (SD)
Age	41.23 years (6.12)
PANSS Total at Baseline	81.13 (13.11)
Number of previous hospitalizations	9.23 (5.22)
Level of Education	10.23 years (3.22)
Gender	Male 84.62% Female 23.07%

RESULTS

- Of the 26 subjects enrolled, data is presented for 20 subjects, as the remaining 6 subjects were missing, or arrested.
- Of the 20 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 4.12 minutes to complete.
- Internal Consistency was high ($\alpha = 0.82$) for the AIS overall scale.
- Preliminary findings show scores on AIS correlated with PANSS G12 ($r = 0.55$, $p = .033$) and with the PANSS Disorganization factor ($r = 0.43$, $p = .020$).
- Test-retest reliability are moderate with ICCs = 0.72.



CONCLUSIONS

- The AIS, with a multidimensional approach, is a short, reliable and valid patient reported measure of insight in schizophrenia. Expert consensus ensures its face and content validity.
- Preliminary 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.