Convergence of Active and Passive Digital Phenoptyping of Changes in Physical Activity in Younger and Older Adults With Schizophrenia In a 52-Week, Open-Label Clinical Trial of Xanomeline and Trospium Chloride

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Methodological Issue Being Addressed Digital phenotyping, including active assessments with remote ecological momentary assessment (EMA) and passive measures are such as facial and vocal expression, GPS, and actigraphy, are being used more commonly in clinical trials. Although these measures appear to have a number of positive features, EMA surveys are essentially unsupervised self-reports. As self -report is challenging in schizophrenia, strategies for evaluation of convergent validity of these EMA reports are important. Further, treatment studies targeting cognition and negative symptoms have sometimes included an upper age limit; in this study we examine the treatment related effects ad convergence of active and passive digital phenotyping in older (Age>44) and younger participants with schizophrenia.

Introduction Previous research has suggested that negative symptoms may worsen with age in schizophrenia. Elements of negative symptoms, such as avolition, anergia, and amotivation, are defined by in part by reduced physical activity. It is important to determine if treatments with demonstrated efficacy have similar effects across the age range in schizophrenia.Thus, we examined age-related differences in physical activity with active and passive digital phenotyping in a 12-month open-label trial with xanomeline/trospium chloride (X/T). We also report month x month changes across in outcomes across older and younger age groups in an effort to understand age-related differences in baseline performance and changes with treatment.

Methods Participants were male and female outpatients with schizophrenia (167 age 45 or older). They answered EMA surveys 3 times per day, 7 days per week, one week per month. On EMA survey days, participants wore an actigraph. EMAs queried location, social context, and activities. EMA-measured activities were characterized as recumbent, seated, standing, and moving and the actigraphy measure was step counts on EMA survey days.

Results There were 350 participants who met the predetermined 33% EMA daily adherence criteria during the baseline period and 312 (89%) who provided actigraphy data on their EMA days. These participants had overall adherence to EMA surveys of 75% during their study participation. The 312 doubly adherent participants answered 33,657 EMA surveys and provided 7957 participant-days of actigraphy. At baseline, older participants were home more frequently

(p<.001), had lower step counts, (p<.001), more recumbent and seated activities (both p<.001) and fewer standing and moving activities (both p<.01). There were treatment-related reductions in recumbent and seated activities, increases in standing and moving activities , (p<.001) and daily steps over 12 months, (p<.001) Step counts were correlated with answering more surveys at home (p<.001) and the frequency of all 4 activities at baseline (p<.001). Changes in step counts correlated with changes in all 4 activities in the expected direction. There was only one significant age x time interaction across all measurements: step counts were found to increase relatively less in older participants (p<.001)

Conclusion Although older participants with schizophrenia started the treatment study with increased sedentary behavior and more commonly being at home compared with younger individuals, the treatment-related benefits were statistically significant and of similar magnitude across age, with only one interaction of age x time. Active and passive digital phenotyping indices were highly correlated at baseline and improved in concert with treatment, suggesting substantial convergent validity. A previous study similar convergence between GPS data and reports of geo-location. There were age-related differences in physical activities related to negative symptoms in schizophrenia, but these features changed with treatment, the potential to lead to improvements in health outcomes as well as everyday functioning.

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Keywords

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Digital Phenotyping
Ecological Momentary Assessment
Actigraphy
Negative Symptoms
Convergent Validity

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Disclosures Dr. Harvey has received consulting fees or travel reimbursements from Alkermes, BMS (Karuna Therapeutics), Boehringer Ingelheim, Kynexis, Minerva Neurosciences, Neurocrine Biosciences, and Recognify.
He has a research grant from Intracellular Therapeutics (Now part of Johnson and Johnson)

He receives royalties from the Brief Assessment of Cognition in Schizophrenia (Owned by Clario, Formerly WCG Endpoint Solutions, Inc, Formerly Verasci, and contained in the MCCB).
He is chief scientific officer of i-Function, Inc and Scientific Consultant to EMA Wellness, Inc.

Drs Chaturvedi, Claxton, Horan, Kaul, Patel, and Sauder, were employees of BMS when this study was conducted.
Mr. Saber is an employee of EMA WEllness