

Title: Procedural and Methodological Issues in Implementing Digital Health Programs in Patients with Schizophrenia.

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Methodological Question: The rapidly expanding field of digital health programs seeks to introduce increasingly affordable and global mobile digital technologies including smartphones, digital apps and wearable devices to enhance psychiatric care and for passive data collection. Smartphone technologies may be able to assist with the monitoring, and treatment of schizophrenia, providing novel and cost-effective interventions with potentially real-time reach. While evidence supports the feasibility of using digital mobile tools in mental health, most studies to date have not reported accessibility, scalability, replicability, User Experience (UX) testing, or subject engagement. Additionally, little is known about the clinical and research reliability of digital health technologies in the care of patients with schizophrenia.

Aims: To evaluate the methodological strengths and weaknesses of implementation of digital health modalities (smartphones for passive data monitoring and ePROs) for schizophrenia.

Methods: Data includes 140 subjects discharged within the past 90 days from a tertiary-care inpatient facility who were eligible for enrollment in a study assessing relapse monitoring using passive digital phenotyping and completion of electronic Patient Report Outcome (ePRO) via an Android app. Feasibility was assessed following review of characteristics related to participants' phone usage prior to study start, symptomatology, compliance rate with ePRO, engagement with digital health app, social support, phone quality, and enrollment rate in relation to eligibility.

Results: Of the 140 eligible subjects, 15.7% (n = 22) were enrolled within 8 months (discharge rate was an average of 10.3 subjects per month, and does not include patients discharged within 90 days prior to study start). Eligible subjects had > 2 inpatient hospitalizations with a mean age of 41.22 (SD = 4.56) years. Barriers to enrollment included not having a cell phone prior to or at the time of discharge (92.8%), not receiving Medicaid benefits within 90 days post discharge, thereby not being able to acquire a government provided phone (30.7%), refusal to participate due to suspiciousness/persecutory delusions regarding tracking activities via smartphone (7.5%). Compliance rate with ePRO assessing awareness of illness (AIS) was 68.75% in completing all weekly assessments since enrollment with an average of 3.66 minutes to complete. Of the enrolled subjects, Interviewers/Clinicians reported having to help 90.9% of subject with phone related technical issues and engagement (ranging from showing

them to use the phone, to using apps, to reinstalling apps, making calls, replacing lost phones). Interviewers/Clinicians also reported the quality of the phones provided resulted in delays in data uploads and data collection for 86.36% of subjects.

Conclusions: Although the current literature on the role of digital health technologies in schizophrenia suggests high feasibility and acceptability, implementation of and engagement with digital devices in individuals with chronic schizophrenia in low-income populations is challenging. With further research and clinical innovation, digital health technologies have the potential to become an important tool that mental health professionals can employ in the clinical care and research of psychotic disorders, specific procedures and methods need to be in place to overcome barriers in the implementation process.