A New Paradigm for Illness Monitoring and Relapse Prevention in Schizophrenia

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Overview of the Study

This study was a 2-arm randomized control trial (RCT) designed to test a multi-modal smartphone data collection system that provided mobile monitoring of schizophrenia to detect early signs of relapse. The RCT compared an arm with participants who received treatment as usual with an arm that received the smartphone system for a year.

One-hundred and fifty one participants were recruited for the 12 months of system deployment. Participants who continued to randomization were randomized to a smartphone arm (n=62) or an arm with treatment as usual (TAU) (n=66). Randomization was conducted by a blinded study statistician. Participants in the smartphone arm met with a researcher to discuss previous relapse incidents and develop a personalized plan for action for when the system flagged relapse risk. A blinded clinical assessor conducted assessments with all participants at baseline and every 3 months post-randomization to assess in-person symptom severity (Brief Psychiatric Rating Scale - BPRS), depression (Calgary Depression Scale for Schizophrenia - CDSS), and social functioning (Social Functioning Scale - SFS). Information from Electronic Medical Records (i.e., hospitalization, ER visits, arrests, medication changes) was also culled every 3 months.

Recruitment

Eligible individuals at a medical clinic were identified through electronic medical records and approached by a staff member to be recruited for the study. Recruitment was open from March 2015 until July 2016.

Inclusion/Exclusion Criteria

Inclusion criteria: 1) Diagnostic and Statistical Manual of Mental Disorders IV (DSM-IV) criteria for schizophrenia, schizoaffective disorder, or psychosis not otherwise specified based on a chart diagnosis, 2) 18 years or older; 3) an inpatient psychiatric hospitalization, daytime psychiatric hospitalization, outpatient crisis management, or short-term psychiatric hospital emergency room within 12 months before study entry; and 4) willing and able to provide informed consent.

Exclusion criteria: 1) Hearing, vision, or motor impairment that make it impossible to operate a smartphone (determined using a demonstration smartphone for screening); and 2) 6th grade reading level (determined by Wide Range Achievement Test - 4th Edition).

Instruments

1. Wide Range Achievement Test Ed. 4 is a brief screening test in which participants read a list of 55 words and receive a grade equivalent rating. Administered only at initial eligibility screening for participation.
2. Participant Demographics. Participants reported age, race, ethnicity, gender, education, history of mobile phone use, etc. to research staff at baseline.

3. Brief Psychiatric Rating Scale (BPRS) is an 18-item scale that rates severity of positive symptoms (including auditory hallucinations and persecutory ideation), and mood and behavioral symptoms. Items were rated by a clinical assessor on a scale of 1 (absent) to 7 (very severe), and yield three scaled scores: positive symptoms, negative symptoms, and general psychopathology. Higher scores indicate worse symptoms. Administered at baseline and every three months.
4. Social Functioning Scale (SFS) is a 76-item questionnaire that assesses various aspects of social functioning and generates a number of subscale scores including social withdrawal, interpersonal behavior, pro-social activities, and an overall score of social functioning. The item values range from 0 (almost never) to 3 (often). A higher score indicates greater social functioning. Administered at baseline and every three months.
5. Calgary Depression Scale for Schizophrenia (CDSS) is a 9-item assessment with values of 0 (absent) to 3 (severe) of depressive symptoms separate from positive, negative and extrapyramidal symptoms in people with schizophrenia. A higher score indicates more severe symptoms. Administered at baseline and every three months.

Participant Remuneration

Participants enrolled in the RCT were compensated $20 for each assessment, but not compensated for actual use of the application. Participants in the smartphone arm were given the smartphone at the end of the study.

Statistical Analysis

Primary outcomes were relapses in participants (defined as one of the following events: psychiatric hospitalization, a significant increase in the level of psychiatric care (i.e. frequency and intensity of services), an increase in medication in addition to a 25% increase in BPRS from last assessment, suicidal or homicidal ideation that was clinically significant in the investigator's judgement, deliberate self-injury, violent behavior resulting in damage to another person or property) and time to relapse (total time from study commencement to first relapse). Relapses were analyzed using logistic regression, adjusting for potential baseline confounding variables. Survival Analysis (Cox Proportional Hazards Models) was used to evaluate time to relapse over the 12-month intervention period. Models were refined by including any baseline factors that may differ between groups as covariates.

Secondary outcomes were psychotic symptom severity (BPRS), depression (CDSS), and social functioning (SFS), as these are salient antecedents to relapse. A mixed-effects model with random intercept and slope was used to test the difference in improvement between the intervention group and the TAU group. This approach takes serial correlation across time into account and does not drop participants from the analysis who have missing assessments or have dropped out. Intervention group (Smartphone vs. TAU), time (coded as 0=baseline, 1=3 months, 2=6 months, 3=9 months, 4=12 months), and group by time interaction were included in the model. Differential improvements were evaluated by the group by time interaction.