

Development of a Mobile System for Self-management of Schizophrenia (SOS) **Randomized Controlled Trial: treatment arm (n=26) Vs control arm (n=25)**

Overview of the Study

This 2-arm RCT piloted a mobile Self-Management of Schizophrenia (SOS) system. Researchers compared an intervention arm using the SOS system and an arm receiving treatment as usual on the outcomes of change in severity of psychotic symptoms and change in social functioning.

Overview of the Smartphone Application Intervention and Features

The mobile application tested in this RCT was developed for smartphones. The final smartphone application design was largely determined by participant feedback provided in focus groups and usability testing.

Recruitment

Individuals with schizophrenia or schizoaffective disorder who were receiving services at the primary study site were recruited through flyers in waiting rooms and bulletin boards at treatment centers, and through referrals from clinical staff. Enrollment was open from November 2015 to July 2016.

Inclusion/Exclusion Criteria

Inclusion criteria were: 1) Chart diagnosis of DSM-IV criteria for schizophrenia or schizoaffective disorder; 2) 18 years or older; 3) prescribed antipsychotic medication; 4) ability (determined by using a competency screener) and willingness to provide informed consent; and 5) a rating of “3” or lower on one of the three items which comprise the *Domination by Symptoms* factor from the Recovery Assessment Scale, indicating patient-rated need for illness self-management. Exclusion criteria were: 1) Hearing, vision, or motor impairment that make it impossible to operate a smartphone or respond to prompts (determined using demonstration smartphone for screening); and 2) English reading level below 4th grade (determined using the Wide Range Achievement Test - 4th Edition).

Randomization and Instruments

Blind clinical raters conducted assessments, and participants were randomized after the baseline assessment to receive 12 weeks of a smartphone intervention or treatment as usual (TAU).

1. Writing and Reading Assessment Test Ed. 4 is a brief screening test in which participants read a list of 55 words and received a grade equivalent rating. Administered only at initial eligibility screening for participation.
2. Psychotic Symptom Rating Scales (PSYRATS) is comprised of 17 items inquiring about the specific dimensions of hallucinations and delusions, with each item being

- rated from 0 (absent) to 4 (severe). The PSYRATS has 2 subscales: the auditory hallucinations subscale (AHS) consisting of 11 items, and the delusions subscale (DS) consisting of 6 items. The measure has a minimum score of 0 and a maximum score of 68, with higher scores indicating worse symptoms. This was administered at baseline and at 12 weeks.
3. Social Functioning Scale (SFS) Social Engagement / Withdrawal and Interpersonal Communication Sub-Scales from the SFS were collected to assess social functioning. These subscales consist of 15 items total. The item values range from 0 (almost never) to 3 (often). A higher score indicates greater social functioning. The SFS was developed for outpatients with schizophrenia. This was administered at baseline and at 12 weeks.
 4. Beck Depression Inventory (BDI) is a 21-question self-report inventory, assessing sleep loss, appetite loss, feelings of being punished, thoughts about suicide, and interest in sex for the past two weeks. This was administered at baseline and at 12 weeks.
 5. Insomnia Severity Index (ISI) is a brief 7-item self-report screening measure of insomnia. The scale is a reliable and valid instrument to quantify perceived insomnia severity. This was administered at baseline and at 12 weeks.
 6. Beliefs about Medicines Questionnaire (BMQ) is a 18-item self-rated questionnaire that uses a 5-point Likert scale to measure patients' concerns about taking their medication and the necessity they feel to take the medication. It also measures more general beliefs or social representations about pharmaceuticals as a class of treatment. This was administered at baseline and at 12 weeks.
 7. Working Alliance Inventory (WAI) is a 12-item scale with 7-point Likert responses that provides an overall measure of alliance between patients and clinical support workers.
 8. Schizophrenia Patient Activation Measure (SPAM) is an adaptation of the Patient Activation Measure (PAM). This measure is 14 items with 5-point Likert responses. It measures confidence in self-management and understanding of the participant's schizophrenia. This was administered at baseline and at 12 weeks.
 9. Participant Demographics Survey Participants reported age, race, ethnicity, gender, education, history of mobile phone use etc. to research staff at the baseline interview.

Participant Remuneration

Participants enrolled in the RCT were compensated for participation in the screening interview (\$15) and (\$30) for each in-person assessment (baseline/12 weeks). Participants were compensated for completion of assessments, not the use of the intervention. The cellular data/text message plans that enabled participants to make calls and send text messages were paid for with study funds.

Statistical Analysis

We tested the difference in improvement between the intervention group and the TAU (treatment as usual) group on two outcomes: psychiatric symptoms and social functioning. A linear mixed

effects model was used for these analyses. This approach takes correlation across time into account and does not drop participants from the analysis who have missing assessments or have dropped out. Intervention group (Mobile Application (SOS) vs. TAU), time (coded as 0 = baseline, 1 =12 weeks), and the group by time interaction was included in the model. Differential improvement between groups was evaluated by the group by time interaction. Due to the small sample size of the study, quantity and direction of the treatment effect (i.e., the effect size), rather than statistical significance, was emphasized in interpretation.