



Off-hours use of a smartphone intervention to extend support for individuals with schizophrenia spectrum disorders recently discharged from a psychiatric hospital

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ABSTRACT

Introduction: Technology-delivered healthcare interventions may enhance dissemination of evidence-based treatments in low-resource areas. These interventions may be accessed ‘on-demand,’ including after hours. Patients with schizophrenia do engage with technological aids but when/how they would utilize these tools is not known.

Methods: We conducted a large, prospective, ten-site, longitudinal study of four technology-assisted interventions for patients with schizophrenia spectrum disorders within 60 days of psychiatric hospital discharge, a high risk period. One tool employed was a smartphone intervention called ‘FOCUS,’ which could be used by patients as needed, providing help in five content areas: medications, mood, social, sleep and voices. Each login was date- and time-stamped as occurring during normal clinic hours, or ‘off-hours,’ and the pattern of use described. **Results:** 347 of 368 patients utilized FOCUS during the 6-month study. There were a total of 75,447 FOCUS logins; 35,739 (47.4%) were self-initiated and 38,139 (50.6%) were off-hours. 18,450 of the logins during off-hours were self-initiated (24.5%). No differences in average usage per month were found based on race/ethnicity. A subset of ‘high utilizers’ (n = 152, 43.8%) self-initiated use of all five FOCUS modules both on- and off-hours. They tended to be women, >35 years old, and had a high school diploma or greater.

Conclusion: Most patients with schizophrenia spectrum disorders recently discharged from the hospital utilized a smartphone intervention targeted to address troublesome residual symptoms. One quarter of the total smartphone utilization was self-initiated off-hours, indicating the potential utility of this tool to extend support for patients during periods of elevated risk.

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1. Introduction

One of the promises of technology-delivered interventions in healthcare is that they may greatly enhance dissemination of evidence-based treatments in areas where health literacy is low and access to specialized care is limited (Akter and Ray, 2010; Kay et al., 2011; Steinhubl et al., 2013). Use of this technology in mental health is rapidly expanding to include interventions for patients with mood and anxiety disorders (Christensen et al., 2002; Luxton et al., 2011; Torous and Powell, 2015; van Straten et al., 2008), as well as schizophrenia-spectrum disorders (Alvarez-Jimenez et al., 2014; Ben-Zeev, 2012; Ben-Zeev et al., 2013a; Firth and Torous, 2015; Kimhy et al., 2012; Sandoval et al., 2017; Treisman et al., 2016). There has been some skepticism that individuals with cognitive deficits associated with schizophrenia would be able to utilize these interventions successfully over time. In previous reports from this study, we found consistent use of a smartphone intervention called 'FOCUS' over a 6-month treatment period (Baumel et al., 2016; Ben-Zeev et al., 2016).

A critically important feature of technology-assisted interventions are that they allow access to needed services on-demand when the patient feels he or she needs them, including after hours when the clinic is closed, at night or on weekends and holidays. One potential benefit of this type of 'just-in-time' intervention is it could provide tangible therapeutic support to patients when direct contact with clinicians is difficult or impossible. However, it is unknown whether patients will use technology-based interventions in mental health to enhance or supplant face-to-face contacts with clinicians, and whether this will be helpful to patients with schizophrenia. We do not claim to definitively answer this question in this analysis, but wanted to begin exploring the implications of 24-hour per day, 7-day per week access to evidence-based interventions.

As access to 24-hour expert clinical support varies significantly from one community to the next, we selected usual business hours as the default metric for this analysis. Given that usual clinic hours are Monday–Friday, 8 AM–5 PM, there are 123 h of a 168-hour week which would be considered 'off-hours.' Assuming patients sleep an average of 8 h per night, this would leave 67 h per week of 'awake' off-hours time compared to 45 h per week of awake 'on-hours' time. We therefore hypothesized more of the self-initiated use of FOCUS would occur during 'off-hours.' To our knowledge, no data has been published to inform whether this assumption is correct. Second, given previous descriptions of a 'digital divide' in which younger individuals are more likely to use smartphone applications and other technologies than older ones (Cresci et al., 2010), we hypothesized that younger patients would be more amenable to the use of a smartphone intervention than older patients. Third, as women utilize health and mental health services more frequently than men do (Galdas et al., 2005; Mackenzie et al., 2006), we hypothesized they would also access smartphone interventions at higher rates. Fourth, based on previous research (DeWalt et al., 2004; Sarkar et al., 2011), we hypothesized patients with lower educational levels would access a technology-delivered health aid less frequently than those with higher levels. Fifth and last, given the underutilization of health and mental health services by minority populations (Wang et al., 2005), we hypothesized minorities would access a smartphone intervention less frequently than Caucasian patients.

2. Methods

2.1. Overview

To address these questions, we conducted a secondary analysis of data obtained from a large, prospective, multicenter longitudinal study of four technology-assisted interventions involving patients with chronic schizophrenia spectrum disorders within 60 days of discharge from a psychiatric hospital following an acute relapse of illness, a period of elevated risk for relapse and re-hospitalization (Weiden and Glazer,

1997). The Health Technology Program (HTP) provided patients with an individualized relapse prevention plan (Mueser and Gingerich, 2011) developed with a mental health technology coach (MHTC) (Ben-Zeev et al., 2015; Mohr et al., 2011), which utilized up to four evidence-based technologies to assist in providing 'just-in-time' support. One of these technologies was a smartphone application called 'FOCUS.' For a full description of these interventions, see Ben-Zeev et al. (2013b, 2014), and Brunette et al. (2016). Sample screen shots of the version of FOCUS used in this study have been published previously in Ben-Zeev et al., 2014, pages 1248–9, and a link to current versions of FOCUS may be found at: <https://www.mh4mh.org/focus>.

We recruited 368 patients from ten community treatment clinics in the U.S. from 2012 to 2015. Participants were assessed at baseline for demographics and clinical characteristics, and followed for 6 months with assessments of symptoms and treatment utilization. This study was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving human subjects and was approved by the appropriate institutional review board governing each site. Each patient signed a comprehensive written informed consent prior to beginning the study.

2.2. Intervention

Following enrollment in the study, during the first 1–2 months (Phase 1) the patient met several times with the MHTC to develop a personalized relapse prevention plan. During the remaining 4–5 months of the 6-month study period (Phase 2) the MHTC continued to be available to assist the patient with trouble-shooting any technology-related questions or other aspects of their relapse prevention plan. Use of the smartphone intervention (FOCUS) was routinely recommended for patients early in the development of the relapse prevention plan, often as the first technology intervention. Study participants were given an android-based smartphone with a prepaid data-plan and taught how to install and use FOCUS on the smartphone. FOCUS provided patients with access to illness management strategies that could: 1) be preprogrammed by the patient and MHTC to 'prompt' use up to three set times per day, or 2) be 'self-initiated' by the patient on-demand when he/she felt the need for help. FOCUS provided guidance to patients in five content areas: medications, mood, social, sleep, and voices. Data on smartphone utilization was collected automatically in the background by the program and uploaded to study servers.

2.3. Measures

Demographic and clinical variables including age, gender, race/ethnicity, marital status, educational attainment, living arrangement, recent work history, number of prior hospitalizations, primary diagnosis, age at first psychotic symptoms/psychiatric illness/psychiatric hospitalization, and current/past substance use were assessed for each participant at baseline.

2.4. Clinical characteristics

Inclusion criteria specified that participants were: English-speaking; age 18–60 years old with a clinical diagnosis of a chronic schizophrenia spectrum disorder (schizophrenia, schizoaffective disorder or psychotic disorder, not otherwise specified); within 60 days of discharge from a psychiatric hospital; and able to provide informed consent. The only exclusion criterion was the presence of a serious medical condition that would preclude safe study participation.

2.5. FOCUS utilization

Each time a participant accessed FOCUS, the date and time-stamped login was recorded within the tool and subsequently coded as occurring either: 1) during 'normal clinic hours', or 2) 'off-hours.' Interactions

with the technology that originated during 'normal clinic hours' were defined as 8 AM to 5 PM, Monday through Friday (excluding weekends and bank holidays), using the local time zone in which the patient was being treated. 'Off-hours' were defined as any access to FOCUS that originated between 5 PM and 8 AM, or any time on weekends or bank holidays.

We were primarily interested in patients' elective use of FOCUS for help with illness self-management (e.g., coping with disturbing symptoms) and thus we restricted our analysis to 'self-initiated' use. FOCUS separately recorded access to each of the five modules, even if accessed sequentially during one contiguous contact. For example, if a patient self-initiated access to FOCUS to seek help in the 'mood' module, then moved on to the 'sleep' module, and finally the 'medication' module before signing off, these uses counted as three contacts in the analysis, because the patient was seeking help for three separate problems.

We further categorized self-initiated use of the technology tools by the following variables: age (18–34, 35–45, or 46–60 years), gender (M, F), marital status, race/ethnicity, educational attainment (<high school or ≥high school), living arrangement, number of prior hospitalizations (<7 or ≥7), work history in the 6 months prior to hospitalization, alcohol, marijuana or other drug use, primary diagnosis, age at onset of psychotic symptoms, age at first psychiatric illness, age at first psychiatric hospitalization, and frequency of self-initiated FOCUS utilization. We evaluated how many times patients accessed care during normal clinic hours compared with off-hours, and further identified and describe a sub-group of patients who were 'high utilizers,' defined by self-initiating use of all five FOCUS modules both during 'off-hours' and 'on-hours.' These patients may constitute a clinical subgroup who benefit disproportionately from access to a smartphone intervention.

2.6. Statistical methods

Descriptive statistics are presented to summarize the use of FOCUS and specific FOCUS modules in the total sample. We then calculated the total number of logins during the study period, broken down into on- and off-hours, and self-initiated vs. auto-prompted use. We also calculated the percentage of users in each group (on- or off-hours) who used all five FOCUS modules, as well as those who used fewer. Chi-square and *t*-tests were used to compare demographic and clinical characteristics at baseline between the high and low FOCUS utilizers. In addition, we compared the high and low utilizer groups on the average number of self-initiated logins per-participant for each of the five FOCUS modules during off- and on-hours using Wilcoxon rank-sum tests.

We hypothesized the patterns of logins would be influenced by age, gender, race/ethnicity and educational attainment and therefore included them as main variables. Other potential correlated factors included: marital status, living arrangement, history of psychiatric hospitalizations, employment status 6 months prior to index hospitalization, and clinical factors such as alcohol, marijuana or other substance use or dependence, diagnoses of schizophrenia, schizoaffective disorder, or psychosis not otherwise specified, age at first psychiatric illness, age at first psychotic symptoms, and age at first psychiatric hospitalization. However, these factors were not statistically significant in the presence of the main variables and hence were omitted in the full models.

The base model for count data is the Poisson regression. However, the distribution of logins was too dispersed for Poisson distribution, and thus we used negative binomial regressions to allow for dispersion. The offset (i.e., a variable with coefficient 1) of the models is a patient's months of "exposure", i.e., the number of months the patient had the opportunity to use the FOCUS tool. The inclusion of the offset term allows us to compare per month use between participants with varying length of follow-up.

For each type of login, we present the number of logins per-person, per-month (or incidence rate per month) and then calculated the incidence rate ratio (IRR) to test for statistically significant differences

between demographic groups. Confidence intervals are based on robust standard errors. In each regression, the independent variables are age, gender, race/ethnicity and education.

3. Results

A total of 368 patients were enrolled in the study, of whom 356 used FOCUS during the 6-month study period. Of the 356 patients who used FOCUS, three ultimately failed screening, three tried to use FOCUS and gave up, and three had less than one month opportunity to use FOCUS due to study closure, leaving 347 patients which comprise our analysis set. Baseline characteristics for these 347 patients are presented in [Table 1](#). Only age, gender, educational level, and age at first psychiatric illness were significantly different between high and low utilizer groups.

Since some patients ($n = 68$, 20%) enrolled close to the end of the study (after 12/1/2014), they did not have full 6-month exposure to FOCUS. Their average exposure to FOCUS was 3.4 months and their average length between first and last login was 2.5 months. For other patients, duration of exposure started at the baseline visit (when the patient was given the program and trained to use it) and ended at their last visit at 6 months. The average length between first and last FOCUS login for all patients was 4.0 months (standard deviation (SD) 1.8) over the 6-month period, with an interquartile range (IQR) from 2.5 to 5.5 months, whereas the average length of exposure was 5.4 months (SD 1.2, IQR from 5.7 to 6 months).

During the study period, participants logged in to FOCUS a total of 75,447 times, of which 35,739 (47.4%) were self-initiated (vs. auto-prompted) and 38,139 (50.6%) were off-hours. 18,450 of the logins during off-hours (24.5%) were self-initiated. 17,289 of the logins during on-hours (46.3%) were self-initiated ([Fig. 1](#)). 313 (90.2%) patients self-initiated access to FOCUS off-hours at least once, and 334 (96.3%) self-initiated access to FOCUS at least once on-hours. The mean number of self-initiated logins per month of exposure was 16.2 (SD = 29.6), and there was no difference between mean self-initiated off-hour logins per month, 8.4 (SD = 16.1), and mean on-hour logins per month, 7.9 (SD = 15.1) ($p = 0.784$). Of the 313 patients who self-initiated logins during off-hours, 60.7% accessed all five FOCUS modules, 13.7% accessed four modules, 8.6% three modules, 8.3% two modules, and 8.6% one module. When compared with 'on-hours' self-initiated use of FOCUS ($n = 334$) the results were similar: 56.3% used all five FOCUS modules, 17.9% used four modules, 9.9% three modules, 9.6% two modules, and 6.3% one module ([Fig. 1](#)).

In analyses assessing the importance of demographic and clinical variables, we found significantly higher rates of use of the different FOCUS modules among females compared to males (IRR 1.6, $p < 0.05$ for self-initiated off-hours use of any FOCUS module, and total FOCUS use, IRR 1.4, $p < 0.05$), patients with higher levels of education compared to those without a high school diploma (IRR 1.7, $p < 0.05$ for any self-initiated off-hours FOCUS use), and patients 35 and older compared to those younger than 35 (IRR 1.9, $p < 0.01$ for 35–45 years and IRR 2.4, $p < 0.001$ for 45 years or older). We found that patients of different race/ethnicity used FOCUS as often on a monthly basis as Caucasian patients. Age at first psychiatric illness was not a statistically significant predictor for use of any module on- or off-hours once we controlled for the main variables of interest. Specific details of these usage patterns are summarized in [Tables 2a, 2b and 3a, 3b](#).

Lastly, we identified a sub-group of 'high-utilizers' ($N = 152$, 43.8% of the total sample) who self-initiated access to all five FOCUS modules both during off- and on-hours ([Table 1](#)). This group utilized the application approximately seven times more often than the rest of the cohort ([Table 4](#) and [Fig. 2](#)). They self-initiated FOCUS use more frequently off-hours (mean 103.8, SD 139.4 for high utilizers vs. mean 13.7, SD 31.1 for low utilizers) as well as on-hours (mean 95.6, SD 132.9 for high utilizers vs. mean 14.1, SD 19.0 for low utilizers). They were characterized as being older, female and more highly educated than those

Table 1
Demographic and clinical variables of those with any FOCUS use (N = 347).

		Total	Low Utilizer	High Utilizer	Chi-square	p-Value
		N = 347	N = 195	N = 152		
		n (%)	n (%)	n (%)		
Age [†]	Less than 35 years	199 (57)	129 (66)	70 (46)	14.2	0.001
	35–45 years	80 (23)	35 (18)	45 (30)		
	Greater than 45 years	68 (20)	31 (16)	37 (24)		
Gender [†]	Male	219 (63)	136 (70)	83 (55)	8.4	0.004
	Female	128 (37)	59 (30)	69 (45)		
Race/ethnicity	Caucasian	171 (49)	90 (46)	81 (53)	2.3	0.513
	African American	87 (25)	50 (26)	37 (24)		
	Other/multi	50 (14)	32 (16)	18 (12)		
	Latino	39 (11)	23 (12)	16 (11)		
Education ^{a,†}	Less than high school diploma	79 (23)	54 (28)	25 (16)	6.5	0.011
	High school diploma or greater	265 (76)	138 (71)	127 (84)		
Number of hospitalizations ^a	Less than 7	189 (54)	102 (52)	87 (57)	0.5	0.468
	7 or greater	152 (44)	88 (45)	64 (42)		
Marital status ^a	Married/sustained conjugal relationship	23 (7)	11 (6)	12 (8)	3.4	0.186
	Widowed/divorced/separated	56 (16)	26 (13)	30 (20)		
	Never married	265 (76)	155 (79)	110 (72)		
Living arrangement ^a	Family	158 (46)	97 (50)	61 (40)	3.7	0.154
	Alone	69 (20)	36 (18)	33 (22)		
	Other	117 (34)	59 (30)	58 (38)		
Working during the 6 months prior to the index hospitalization ^a		37 (19)	75 (22)	38 (25)	1.6	0.201
Currently using alcohol ^a		26 (13)	54 (16)	28 (18)	1.5	0.217
Currently using marijuana ^a		25 (13)	47 (14)	22 (14)	0.2	0.697
Currently alcohol, cannabis or other substance dependence or abuse		49 (25)	84 (24)	35 (23)	0.2	0.650
Ever been treated as an outpatient or been hospitalized for drug or alcohol problems ^a		50 (26)	91 (26)	41 (27)	0.0	0.846
Diagnosis of schizophrenia		172 (50)	97 (50)	75 (49)	0.0	0.941
Diagnosis of schizoaffective disorder		159 (46)	86 (44)	73 (48)	0.5	0.467
Diagnosis of psychosis, not otherwise specified		22 (10)	12 (9)	10 (10)	0.1	0.815

	Mean (SD)	Mean (SD)	Mean (SD)	t-Test	p-Value
Age at first psychiatric illness [†]	18.7 (8.2)	17.8 (7.9)	19.8 (8.3)	2.2	0.026
Age at first psychotic symptoms	21.1 (8.5)	20.7 (8.3)	21.6 (8.7)	0.9	0.344
Age at first psychiatric hospitalization	22.8 (7.9)	22.2 (8.1)	23.6 (7.5)	1.6	0.106

^a Numbers do not add up to the total in some columns due to missing data.

[†] Statistically significantly different between low- and high-utilizers at $p \leq 0.05$, based on chi-square test for discrete variables and *t*-test for continuous variables.

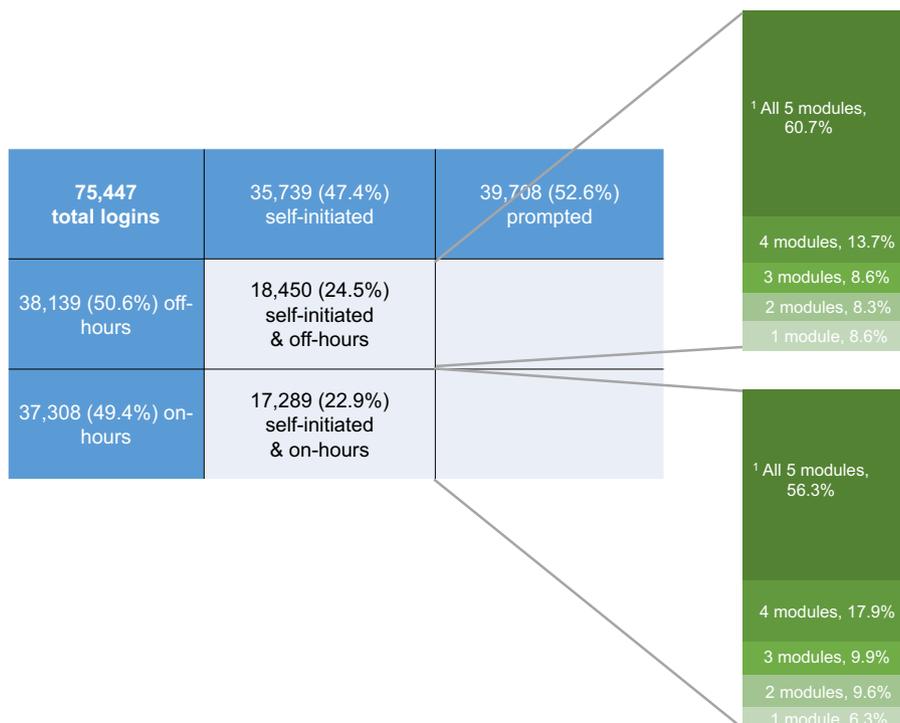


Fig. 1. FOCUS intervention logins by prompted vs self-initiated, and on- vs off-hours usage. ¹The five FOCUS modules were: medications, mood, sleep, social, and voices.

Table 2a
Number of self-initiated off-hour logins per month [95% confidence interval] in the 6-month period.

		Any module	Medication	Mood	Sleep	Social	Voice
Age	Less than 35 years	6.8 [5.2,8.4]	1.3 [1.0,1.6]	1.8 [1.4,2.2]	1.3 [0.9,1.6]	1.3 [0.9,1.6]	1.1 [0.8,1.4]
	35–45 years	12.7 [8.2,17.3]	2.1 [1.3,2.8]	3.2 [2.1,4.2]	2.3 [1.4,3.2]	2.7 [1.6,3.8]	2.6 [1.6,3.5]
	Greater than 45 years	16.3 [9.3,23.2]	3.1 [1.7,4.5]	3.8 [2.3,5.4]	2.9 [1.6,4.3]	3.4 [1.9,4.9]	3.1 [1.6,4.6]
Gender	Male	8.3 [6.1,10.5]	1.6 [1.2,2.0]	2.0 [1.5,2.5]	1.5 [1.0,1.9]	1.7 [1.2,2.2]	1.6 [1.1,2.0]
	Female	12.9 [9.6,16.2]	2.3 [1.6,2.9]	3.3 [2.5,4.1]	2.4 [1.8,3.1]	2.6 [1.8,3.3]	2.3 [1.6,3.0]
Race/ethnicity	Caucasian	10.1 [7.5,12.6]	1.9 [1.4,2.5]	2.5 [1.9,3.1]	1.8 [1.3,2.2]	2.0 [1.4,2.5]	1.9 [1.3,2.4]
	African American	10.5 [6.6,14.3]	1.8 [1.2,2.4]	2.6 [1.7,3.4]	1.9 [1.2,2.7]	2.1 [1.2,3.0]	2.1 [1.2,3.0]
	Other/multi	7.2 [3.6,10.8]	1.2 [0.7,1.7]	1.8 [0.9,2.6]	1.3 [0.5,2.0]	1.4 [0.6,2.2]	1.6 [0.7,2.5]
	Latino	14.7 [6.3,23.0]	2.6 [1.1,4.1]	4.1 [1.5,6.6]	3.1 [1.0,5.2]	3.4 [1.5,5.2]	1.8 [0.7,2.8]
Education	Less than high school diploma	6.6 [4.1,9.0]	1.2 [0.7,1.7]	1.7 [1.1,2.2]	1.1 [0.7,1.5]	1.2 [0.7,1.7]	1.4 [0.8,2.0]
	High school diploma or greater	11.2 [8.7,13.6]	2.0 [1.6,2.5]	2.8 [2.2,3.4]	2.1 [1.6,2.6]	2.3 [1.7,2.8]	2.0 [1.5,2.5]

The models are based negative binomial regression with age, gender, race/ethnicity and education. N = 344 due to missing values in education for three patients.

who were not as fully engaged in using FOCUS. Adjusting for age, gender, race/ethnicity and education, the IRRs are statistically significant for all modules between high and low utilizers for both on- and off-hour use and total logins (Table 4 and Fig. 2).

4. Discussion

Patients with schizophrenia spectrum disorders recently discharged from a psychiatric hospital utilized a smartphone application frequently as part of a personalized relapse prevention plan (75,447 times) during the 6-month study period, with a mean of 16.2 (SD = 29.6) self-initiated logins per month of exposure. 47.4% of the total logins were self-initiated, and 24.5% were self-initiated off-hours. To our knowledge this is the largest study of an mHealth intervention targeted to address illness management in patients with schizophrenia spectrum disorders, and the first to assess off-hour, patient-driven use. Subjects in this study accessed FOCUS half the time (38,139 times, 50.6%) during off-hours, indicating that approximately half the 'dose' of this intervention occurred

when the clinic was closed, an important extension of care during times when access to a clinician may be difficult or impossible. Participants used FOCUS as often during on-hours suggesting they may have used this intervention during times of need irrespective of clinic hours. It is possible they self-initiated use of FOCUS during usual business hours because it was easy to use and more convenient than accessing clinic-based care, or to avoid the stigma associated with seeking care in person (Corrigan, 2004; Lange et al., 2000). A potential advantage of home-delivered care via technology is privacy and convenience. Furthermore, the evidence-based illness management strategies offered in FOCUS may not have been available through other means at the clinics. These suppositions warrant further investigation.

Surprisingly, those 35 years and older used the application more frequently than those under age 35 across all self-initiated domains: off-hours, on-hours, and total use. These data counter impressions of the 'digital divide' in which younger users would be most likely to access help via a cell phone application. Other authors have observed a closing of the divide and a willingness of older patients to use their cell phones

Table 2b
Incidence rate ratio (IRR) for self-initiated off-hour logins per month [95% confidence interval] in the 6-month period.

		Any module	Medication	Mood	Sleep	Social	Voice
Age	Less than 35 years	Reference	Reference	Reference	Reference	Reference	Reference
	35–45 years	1.9 ^b [1.2,2.9]	1.6 ^a [1.0,2.4]	1.8 ^b [1.2,2.7]	1.8 ^a [1.1,2.8]	2.1 ^b [1.3,3.4]	2.3 ^c [1.4,3.7]
	Greater than 45 years	2.4 ^c [1.5,3.9]	2.4 ^c [1.4,4.0]	2.1 ^b [1.3,3.4]	2.3 ^b [1.4,3.9]	2.7 ^c [1.6,4.5]	2.8 ^c [1.6,4.8]
Gender	Male	Reference	Reference	Reference	Reference	Reference	Reference
	Female	1.6 ^a [1.1,2.2]	1.4 [1.0,2.0]	1.7 ^b [1.2,2.3]	1.7 ^b [1.2,2.4]	1.5 ^a [1.0,2.2]	1.5 [1.0,2.2]
Race/ethnicity	Caucasian	Reference	Reference	Reference	Reference	Reference	Reference
	African American	1.0 [0.7,1.6]	0.9 [0.6,1.4]	1.0 [0.7,1.5]	1.1 [0.7,1.7]	1.1 [0.7,1.7]	1.1 [0.7,1.9]
	Other/multi	0.7 [0.4,1.2]	0.6 [0.4,1.0]	0.7 [0.4,1.2]	0.7 [0.4,1.3]	0.7 [0.4,1.3]	0.9 [0.5,1.5]
	Latino	1.5 [0.8,2.7]	1.3 [0.7,2.5]	1.6 [0.8,3.2]	1.8 [0.9,3.6]	1.7 [0.9,3.1]	1.0 [0.5,1.8]
Education	Less than high school diploma	Reference	Reference	Reference	Reference	Reference	Reference
	High school diploma or greater	1.7 ^a [1.1,2.6]	1.7 ^a [1.1,2.6]	1.7 ^a [1.1,2.5]	1.9 ^b [1.3,3.0]	1.9 ^b [1.2,2.9]	1.4 [0.9,2.3]

The models are based negative binomial regression with age, gender, race/ethnicity and education. N = 344 due to missing values in education for three patients.

^a p < 0.05.
^b p < 0.01.
^c p < 0.001.

Table 3a
Number of self-initiated on-hour logins per month [95% confidence interval] in the 6-month period.

		Any module	Medication	Mood	Sleep	Social	Voice
Age	Less than 35 years	6.4 [4.9,7.8]	1.1 [0.9,1.4]	1.7 [1.3,2.1]	1.1 [0.8,1.4]	1.3 [0.9,1.6]	1.1 [0.8,1.4]
	35–45 years	11.7 [7.3,16.1]	2.0 [1.3,2.8]	3.1 [2.0,4.2]	2.0 [1.2,2.7]	2.3 [1.3,3.3]	2.4 [1.3,3.5]
	Greater than 45 years	15.2 [9.7,20.8]	2.7 [1.7,3.7]	3.8 [2.6,5.1]	2.9 [1.7,4.2]	3.0 [1.9,4.2]	2.9 [1.7,4.2]
Gender	Male	8.4 [6.3,10.5]	1.6 [1.2,2.0]	2.0 [1.6,2.5]	1.5 [1.1,2.0]	1.6 [1.2,2.0]	1.6 [1.1,2.1]
	Female	10.8 [8.3,13.3]	1.7 [1.3,2.1]	3.1 [2.4,3.8]	1.9 [1.4,2.4]	2.2 [1.6,2.8]	1.9 [1.3,2.5]
Race/ethnicity	Caucasian	8.8 [6.7,11.0]	1.7 [1.3,2.1]	2.3 [1.7,2.8]	1.4 [1.1,1.8]	1.7 [1.2,2.2]	1.7 [1.2,2.2]
	African American	10.5 [6.4,14.5]	1.6 [1.1,2.1]	2.7 [1.8,3.6]	2.0 [1.1,2.9]	2.1 [1.2,3.1]	2.1 [1.1,3.1]
	Other/multi	6.2 [4.1,8.3]	1.2 [0.7,1.6]	1.5 [1.0,2.0]	1.1 [0.7,1.6]	1.0 [0.6,1.4]	1.4 [0.7,2.1]
	Latino	14.2 [6.8,21.6]	2.0 [0.9,3.2]	4.4 [2.1,6.6]	3.1 [1.2,5.0]	3.1 [1.5,4.7]	1.8 [0.6,3.0]
Education	Less than high school diploma	7.3 [4.9,9.7]	1.3 [0.9,1.8]	1.9 [1.3,2.4]	1.2 [0.7,1.6]	1.4 [0.9,2.0]	1.5 [0.8,2.1]
	High school diploma or greater	9.9 [7.9,12.0]	1.7 [1.4,2.1]	2.6 [2.1,3.1]	1.8 [1.4,2.3]	2.0 [1.5,2.4]	1.8 [1.4,2.3]

The models are based negative binomial regression with age, gender, race/ethnicity and education. N = 344 due to missing values in education for three patients.

for purpose-driven, help-seeking behaviors, especially when coached in how to use the device, as was done in this study (Czaja and Lee, 2007; Parker et al., 2013; Seto et al., 2010; Ybarra and Eaton, 2005). Our study supports offering a smartphone intervention to patients with schizophrenia spectrum disorders of all ages, as patients older than 35 years engaged well with FOCUS when given ongoing technical support from the mental health technology coach, if needed.

Female patients also consistently self-initiated use of any FOCUS module more often during both on- and off-hours than did male patients. They also used the mood and social modules more often than males during ‘on-hours.’ This finding is unsurprising as women tend to access preventative health and mental health care, including mHealth applications, more consistently than men (Guo et al., 2015).

African Americans and Latinos used ‘any’ module as often as Caucasians and non-Latinos, both off- and on-hours. This is a hopeful sign as results from other studies of telehealth interventions in African American populations have been mixed (Juzang et al., 2011; Migneault et al., 2012; Saberi et al., 2013; Trief et al., 2013). Latinos of

both genders have shown a willingness to use mHealth interventions if available and directed to topics of concern (Burner et al., 2013; Kanter et al., 2014; Price et al., 2013). These findings are encouraging since engaging minority populations equally in healthcare has historically been a challenge, and the usage pattern in this study highlights the potential power of technological aids, like cell phone applications, to reach these traditionally underserved patient populations. Furthermore, African Americans and Latinos are among the most active users of the mobile internet (Mitchell et al., 2014; Sarasohn-Kahn, 2010), and when assured access to the same mHealth intervention as in our study, used FOCUS as often as Caucasians. We eliminated barriers presented by socioeconomic limitations by giving each study participant a free smartphone and data plan. This may limit the generalizability of our findings since economically disadvantaged patients may not have access to smartphones. However, smartphones sales are projected to reach 5.8 billion units worldwide by 2020 with 71% coverage by mobile broadband. Further, there are expected to be 8 billion mobile broadband subscriptions by 2022, accounting for 90% of the market share

Table 3b
Incidence rate ratio (IRR) for self-initiated on-hour logins per month [95% confidence interval] in the 6-month period.

		Any module	Medication	Mood	Sleep	Social	Voice
Age	Less than 35 years	Reference	Reference	Reference	Reference	Reference	Reference
	35–45 years	1.8 ^b [1.2,2.8]	1.8 ^b [1.2,2.7]	1.8 ^b [1.2,2.7]	1.8 ^a [1.1,2.7]	1.8 ^a [1.1,3.0]	2.3 ^b [1.3,3.8]
	Greater than 45 years	2.4 ^c [1.6,3.7]	2.3 ^c [1.5,3.7]	2.3 ^c [1.5,3.3]	2.6 ^c [1.6,4.3]	2.4 ^c [1.5,3.8]	2.7 ^c [1.7,4.5]
Gender	Male	Reference	Reference	Reference	Reference	Reference	Reference
	Female	1.3 [0.9,1.8]	1.1 [0.8,1.5]	1.5 ^b [1.1,2.1]	1.2 [0.9,1.8]	1.4 [1.0,2.0]	1.2 [0.8,1.7]
Race/ethnicity	Caucasian	Reference	Reference	Reference	Reference	Reference	Reference
	African American	1.2 [0.8,1.9]	0.9 [0.6,1.4]	1.2 [0.8,1.8]	1.4 [0.8,2.3]	1.2 [0.7,2.1]	1.3 [0.7,2.3]
	Other/multi	0.7 [0.5,1.0]	0.7 [0.4,1.0]	0.7 ^a [0.5,1.0]	0.8 [0.5,1.2]	0.6 ^a [0.4,0.9]	0.9 [0.5,1.5]
	Latino	1.6 [0.9,2.8]	1.2 [0.7,2.2]	1.9 ^a [1.1,3.4]	2.2 ^a [1.1,4.1]	1.8 ^a [1.0,3.2]	1.1 [0.6,2.2]
Education	Less than high school diploma	Reference	Reference	Reference	Reference	Reference	Reference
	High school diploma or greater	1.4 [0.9,2.0]	1.3 [0.9,1.9]	1.4 [1.0,2.0]	1.6 ^a [1.0,2.4]	1.4 [0.9,2.1]	1.2 [0.8,2.0]

The models are based negative binomial regression with age, gender, race/ethnicity and education. N = 344 due to missing values in education for three patients.

^a p < 0.05.
^b p < 0.01.
^c p < 0.001.

(Ewaldsson, 2016; GSMA mobile economy, 2016), eventually replacing other mobile devices, even for resource-poor populations.

In terms of educational status, those with a high school diploma or greater consistently self-initiated off-hours and total use (data available upon request) of any FOCUS module more than those with less than a high school diploma, but did not differ in their use of FOCUS on-hours. Individuals with low levels of educational attainment typically have worse health outcomes (Backlund et al., 1999; Leaf et al., 1987; Muller, 2002) and our study highlights the challenge of convincing this group to seek help and self-initiate access to care. These findings may suggest that patients with lower educational attainment need assistance in processing and understanding illness management strategies since reading level in some health interventions has been too high to facilitate comprehension (Kisely et al., 2003; Sudore et al., 2006). In addition, for this group, working in the absence of a highly trained clinician may be suboptimal (Rubinstein et al., 2016). Newer versions of the FOCUS intervention include voice and video-based content to try to address this limitation.

Finally, we identified a cohort of users who self-initiated use of all five modules of FOCUS both off- and on-hours. These were defined as 'high utilizers' and were more likely to be over 35 years of age, female, have a high school degree or greater, and older at the time of first psychiatric illness. This subgroup may be particularly amenable to smartphone interventions like FOCUS. Whether different design or content features would be more appealing to younger patients, men, and those with lower educational attainment requires additional investigation. We believe this type of analysis ('high' vs. 'low' utilizers) may facilitate the development and appropriate dissemination of technology-based interventions to those most likely to use them and may constitute an important standard for evaluation of these tools going forward.

4.1. Limitations

One of the limitations of this analysis is that we did not ask patients specifically *why* they accessed a particular FOCUS module on a particular day of the week or a particular time of day. Thus, we are left to try to infer patients' intentions using our best clinical judgment. For example, patients may have self-initiated access to FOCUS on- and off-hours because they were bored, not because they were experiencing an exacerbation of symptoms. This is supported by the observation that there were no statistically significant differences in use of each of the five FOCUS modules off- vs. on-hours, suggesting patients may have selected modules at random, rather than to cope with a specific, troubling symptom. Conversely, patients may have been so impaired by symptoms, that they could not self-initiate contact with FOCUS, in which case, auto-prompted interactions would be more clinically useful.

Second, it is not possible to tease out the clinical utility of the FOCUS intervention alone as it was given in the context of a comprehensive relapse prevention plan involving other technological aids. Any improvement in patient function that may have occurred cannot, therefore, be attributed solely to the use of FOCUS. While we cannot guarantee that meaningful clinical benefit was derived from each login to FOCUS, there is evidence to suggest that providing repeated, simple concepts in the service of over-learning is an effective illness management strategy for patients with schizophrenia (Bellack and DiClemente, 1999; Kopelowicz et al., 2006). Future studies would need to be conducted to assess the relative clinical utility of each unique part of the packaged intervention.

Lastly, FOCUS was only available for use in English-speaking participants. For this intervention to have an impact globally it will need to be translated to other languages in a culturally sensitive manner and validated in those populations. Extension of this work in other languages and cultures would be another important goal for future work.

5. Conclusion

Smartphone applications may function as a useful adjunctive support for patients with schizophrenia during both on- and off-hours. The fact that half of the self-initiated logins to FOCUS occurred after hours signals an important extension, or dose, of additional care that patients otherwise may not have been able to receive. Additionally, African American and Latino participants used the application as often as Caucasians, indicating this may be a promising way to bring specialized, evidence-based mental health care interventions to traditionally underserved minority populations. The smartphone intervention studied here was used most frequently by patients who were female, older than 35, more highly educated, and who had a later onset of psychiatric illness, indicating a subgroup of patients for whom this form of symptom management may be particularly appealing. Further work will be needed to assess additional important clinical variables that may predict use and acceptability of technology-based interventions in healthcare. Future studies to elicit the reasons why patients choose to access specific mHealth interventions both off and on-hours, as well as validation of

Table 4

Mean number and standard deviation of self-initiated logins: total and stratified by 'high' vs. 'low' utilizers.

	Total N = 347	Low utilizer N = 195	High utilizer ^a N = 152	z-Statistic	p-Value
Total number of self-initiated use					
Medication	18.7 (35.8)	7.0 (16.0)	33.7 (47.0)	12.6	<0.001
Mood	26.1 (45.4)	8.2 (12.9)	49.0 (59.8)	12.7	<0.001
Sleep	18.6 (38.3)	4.3 (10.9)	37.0 (51.0)	14.0	<0.001
Social	20.5 (42.1)	5.5 (14.6)	39.7 (55.9)	13.0	<0.001
Voice	19.1 (41.7)	2.8 (4.9)	40.0 (56.3)	14.2	<0.001
Any module	103.0 (193.3)	27.8 (46.1)	199.4 (257.3)	13.6	<0.001
Total number of off-hour self-initiated use					
Medication	9.9 (20.9)	3.4 (11.1)	18.1 (26.9)	12.7	<0.001
Mood	13.2 (24.6)	3.8 (7.3)	25.3 (32.6)	12.8	<0.001
Sleep	9.7 (20.5)	2.2 (7.1)	19.2 (27.1)	13.8	<0.001
Social	10.6 (22.8)	2.8 (10.8)	20.6 (29.3)	13.3	<0.001
Voice	9.8 (21.8)	1.4 (2.8)	20.6 (29.5)	14.0	<0.001
Any module	53.2 (104.9)	13.7 (31.1)	103.8 (139.1)	13.6	<0.001
Total number of on-hour self-initiated use					
Medication	8.8 (16.7)	3.5 (6.7)	15.6 (22.3)	11.4	<0.001
Mood	12.9 (23.0)	4.4 (6.4)	23.7 (30.9)	11.4	<0.001
Sleep	9.0 (19.5)	2.1 (4.6)	17.8 (26.5)	13.1	<0.001
Social	9.9 (21.8)	2.7 (5.0)	19.1 (30.1)	12.0	<0.001
Voice	9.3 (22.2)	1.4 (2.7)	19.4 (30.5)	13.6	<0.001
Any module	49.8 (97.7)	14.1 (19.0)	95.6 (132.9)	12.8	<0.001
Mean number of self-initiated use per month					
Medication	3.5 (6.3)	1.3 (3.0)	6.2 (8.1)	12.3	<0.001
Mood	4.9 (8.1)	1.8 (3.0)	9.0 (10.5)	12.1	<0.001
Sleep	3.5 (6.8)	0.8 (1.9)	6.8 (8.9)	13.5	<0.001
Social	3.8 (7.5)	1.1 (2.6)	7.3 (9.8)	12.5	<0.001
Voice	3.6 (7.4)	0.6 (1.2)	7.4 (9.9)	13.7	<0.001
Any module	19.3 (34.2)	5.7 (8.8)	36.8 (45.1)	13.1	<0.001
Mean number of off-hour self-initiated use per month					
Medication	1.8 (3.6)	0.7 (2.0)	3.3 (4.6)	12.5	<0.001
Mood	2.5 (4.5)	0.8 (1.5)	4.7 (5.9)	12.3	<0.001
Sleep	1.8 (3.7)	0.4 (1.2)	3.6 (5.0)	13.4	<0.001
Social	2.0 (4.2)	0.6 (1.9)	3.9 (5.4)	12.9	<0.001
Voice	1.9 (4.0)	0.3 (0.6)	3.9 (5.4)	13.6	<0.001
Any module	10.0 (19.0)	2.7 (5.6)	19.3 (25.1)	13.2	<0.001
Mean number of on-hour self-initiated use per month					
Medication	1.6 (3.0)	0.7 (1.3)	2.9 (3.9)	11.2	<0.001
Mood	2.4 (4.1)	1.0 (1.6)	4.3 (5.4)	10.7	<0.001
Sleep	1.7 (3.4)	0.4 (0.8)	3.2 (4.6)	12.6	<0.001
Social	1.8 (3.8)	0.6 (1.0)	3.5 (5.2)	11.4	<0.001
Voice	1.8 (3.9)	0.3 (0.8)	3.6 (5.3)	13.1	<0.001
Any module	9.3 (17.1)	2.9 (3.9)	17.5 (23.1)	12.2	<0.001

p-Values are based on the Wilcoxon rank-sum (Mann-Whitney) test.

^a 'High utilizers' are defined as those who self-initiated logins to all 5 FOCUS modules both on- and off-hours.

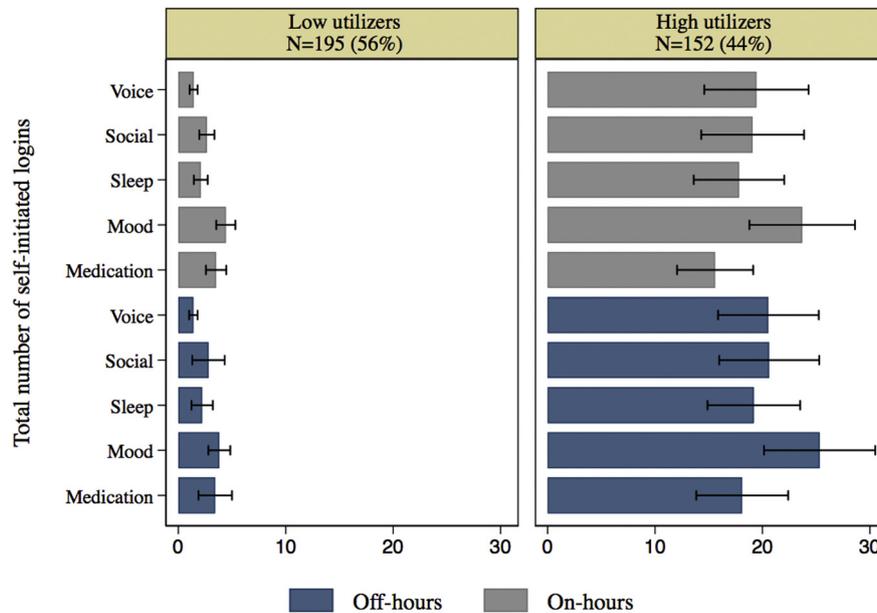


Fig. 2. Mean total number of self-initiated logins in the 6-month study period; stratified by 'high' and 'low' utilizers with standard error bars. Comparisons between high and low utilizers by the Wilcoxon rank-sum test are all statistically significant with p -values <0.001 .

these tools in other cultures and non-English speaking populations, are also needed to further assess its clinical utility.

Conflict of interest

Dr. Achtyes has received research support from Alkermes, AssurEx, Astellas, Avanis, Boehringer Ingelheim, Janssen, Neurocrine Biosciences, Novartis, Otsuka, Pfizer, Pine Rest Foundation, Priority Health, Network180 and Vanguard Research Group and has served on advisory panels for Alkermes, Roche, Janssen, Neurocrine Biosciences and the Vanguard Research Group. Dr. Ben-Zeev has an intervention content licensing agreement with Pear Therapeutics. Dr. Brunette receives research support from Alkermes. Dr. Robinson has been a consultant or received grants from Asubio, Bristol-Myers Squibb, Janssen, Otsuka, and Shire. Ms. Marcy is a stockholder in Pfizer. Dr. Schooler has served on advisory boards for Alkermes, Forum (formerly EnVivo), and Sunovion. Dr. Kane has been a consultant for or has received honoraria from Alkermes, Eli Lilly, EnVivo Pharmaceuticals (Forum), Forest, Genentech, H. Lundbeck, Intracellular Therapeutics, Janssen Pharmaceuticals, Johnson and Johnson, Otsuka, Reviva, Roche, Sunovion, and Teva and is a shareholder in Med-Avante, Inc., LB Pharmaceuticals and Vanguard Research Group. The other authors report no financial relationships with commercial interests.

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CRediT authorship contribution statement

Eric D. Achtyes: Data curation, Formal analysis, Funding acquisition, Investigation, Writing - original draft, Writing - review & editing. **Dror Ben-Zeev:** Data curation, Methodology, Investigation, Writing - review & editing. **Zhehui Luo:** Formal analysis, Investigation, Writing - review & editing. **Heather Mayle:** Data curation, Investigation, Project administration, Writing - review & editing. **Brandi Burke:** Formal analysis, Investigation, Writing - review & editing. **Armando J. Rotondi:** Data curation, Methodology, Investigation, Writing - review & editing. **Jennifer D. Gottlieb:** Data curation, Methodology, Investigation, Writing - review & editing. **Mary F. Brunette:** Methodology, Investigation, Writing - review & editing. **Kim T. Mueser:** Conceptualization, Methodology, Investigation, Writing - review & editing. **Susan Gingerich:** Methodology, Investigation, Writing - review & editing. **Piper S. Meyer-Kalos:** Methodology, Investigation, Writing - review & editing. **Patricia Marcy:** Conceptualization, Methodology, Investigation, Project administration, Writing - review & editing, Data curation. **Nina R. Schooler:** Conceptualization,

Methodology, Investigation, Project administration, Writing - review & editing. **Delbert G. Robinson:** Conceptualization, Methodology, Investigation, Project administration, Writing - review & editing, Data curation. **John M. Kane:** Conceptualization, Methodology, Funding acquisition, Investigation, Project administration, Writing - review & editing, Data curation.

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