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Enhancing early psychosis treatment using smartphone technology: A longitudinal feasibility and validity study

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ABSTRACT

Smartphone applications that promote symptom tracking and self-management may improve treatment of serious mental illness (SMI). Although feasibility has been established in chronic adult outpatient or inpatient SMI samples, no data exist regarding implementation of smartphone technology in adolescent and young adult populations as part of early psychosis (EP) outpatient care. We implemented a smartphone "app" plus clinician Dashboard as an add-on treatment tool in the University of California, Davis Early Psychosis Program. Participants completed daily and weekly surveys examining mood, symptoms, and treatment relevant factors via the app for up to 14 months. Clinicians discussed symptom ratings and surveys during regular treatment sessions using the Dashboard. We report methodological details of the study, feasibility metrics, and analyses of the validity of measuring symptoms via self-report using mobile health (mHealth) technology in comparison to gold-standard clinician-rated interviews based on a comprehensive longitudinal analysis of within-person data. Results demonstrate that integrating mHealth technology into EP care is feasible and self-report assessment of symptoms via smartphone provides symptom data comparable to that obtained via gold-standard clinician-rated assessments.

1. Introduction

Smartphone applications that promote symptom tracking, treatment engagement, and self-management have the potential to improve mental health outcomes and reduce cost of care (Luxton et al., 2011). This is especially important in the treatment of psychotic illness, as long-term clinical outcomes remain poor and financial costs are high (Bartels et al., 2003; Desai et al., 2013). A growing body of work is testing mobile technologies designed to enhance clinical care and self-management in psychotic and other serious mental illnesses (SMI) (Depp et al., 2016).

Research demonstrates utilization of smartphone applications and associated mobile technology in SMI is achievable. Individuals with psychosis are amenable to using a variety of technologies, even when symptomatic, and study completion rates and compliance are high (Ben-Zeev, 2012; Depp et al., 2016). Although the evidence supports feasibility (Ben-Zeev et al., 2014; Palmier-Claus et al., 2012), most studies evaluate adoption of technology independent of care providers, and have almost exclusively been conducted in chronic adult outpatient or inpatient samples (Alvarez-Jimenez et al., 2014). Given the emphasis on early intervention in psychosis (IEPA-Writing-Group, 2005), implementation in adolescent and young adult populations in the early stages of psychotic illness is critical. Similarly, successful implementation and long-term adoption of mobile technology likely requires integration into clinical care settings so that it is directly relevant and personalized to each individual's treatment plan (Palmier-Claus et al., 2013). This may be particularly important for relapse prevention, a major challenge in the treatment of early psychosis (EP), which represents the critical period for intervention within the first 2–5 years after illness onset (McGorry, 2015).

Although remission of psychotic symptoms following the initial psychotic episode is achievable (Masand et al., 2009), 50% of patients relapse within two years; 80% relapse within five (Eisner et al., 2013). Predictors of relapse amenable to treatment include symptom exacerbations (Birchwood et al., 2000), medication adherence (Masand et al., 2009), and social impairments (Corrigan and Phelan, 2004). Approximately two weeks prior to acute symptom exacerbation, patients often show an increase in "early signs," including visual/auditory

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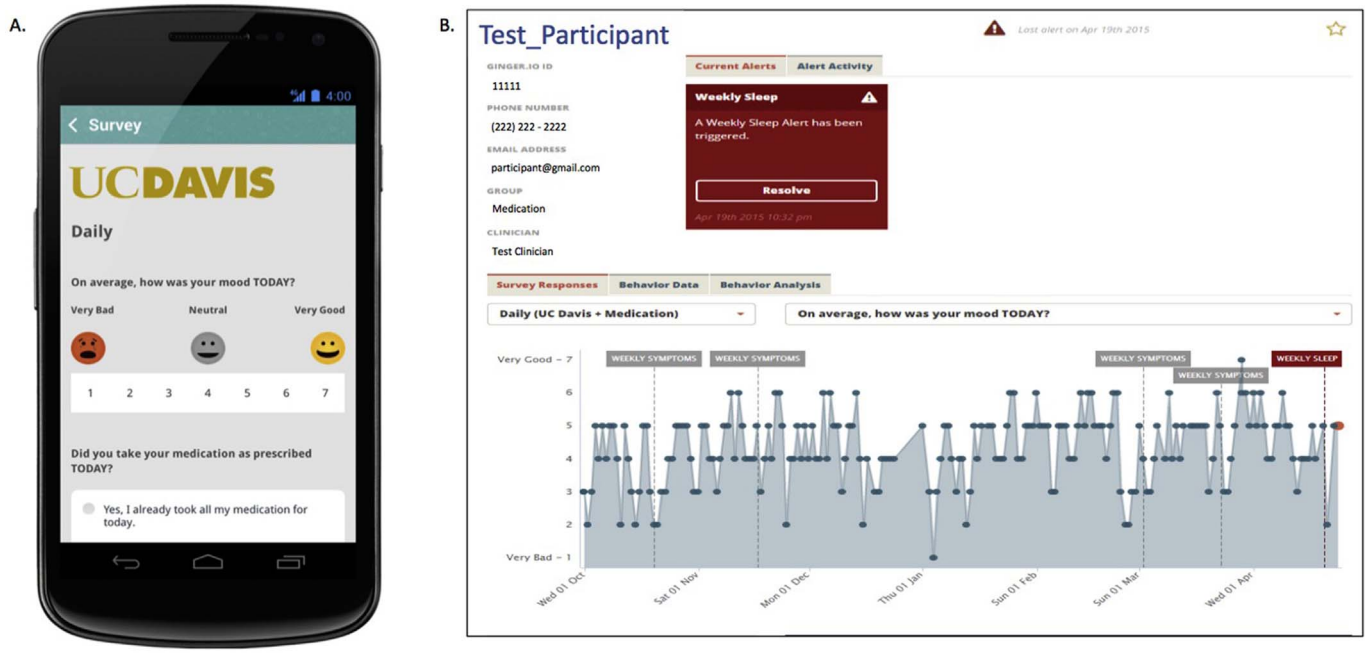

Fig. 1. A. Example App view. Participants responded to daily and weekly surveys in the app. Responses were summarized on the Dashboard and discussed with clinicians as part of regular clinic appointments. B. Example Dashboard view. Clinicians received "alerts" when responses were considered clinically significant. Alerts were resolved according to patient's need for care. Clinicians could plot symptoms over time (daily mood shown). Alerts are flagged on the plot.

perceptions, anxiety/dysphoria, insomnia, increased emotional reactivity, mild subjective cognitive problems, and difficulties tolerating normal stress (Birchwood et al., 1989; Eisner et al., 2013). Regular and close monitoring of these predictors could enable early intervention to minimize the impact of relapse, or prevent it altogether.

However, without the information necessary to identify individuals in need of such intervention, providers have limited ability to respond rapidly. In the typical outpatient clinic, weekly evaluations (at best; most clinics conduct monthly or bi-annual assessments) provide an incomplete snapshot of patient status and providers may miss early signs of relapse. Retrospective ratings may miss day-to-day fluctuations in mood and behavior (Ben-Zeev, 2012) and repeated questioning by providers may be perceived as challenging or stressful by patients, who may have difficulty recalling their previous experiences or prefer to report symptoms remotely (Palmier-Claus et al., 2013). Gathering relevant data daily via a smartphone application and making it available via a secure web-based platform could enable providers to identify patients most in need of intervention without the burden of increased appointments. However, before smartphone data can be used to predict relapse and prompt early intervention, the validity of assessing early signs of relapse via smartphone (as opposed to traditional face-to-face clinical assessment) must be established.

To test the potential utility of symptom assessment via mHealth technology, we implemented a smartphone application plus clinician Dashboard as an add-on treatment tool within the Coordinated Specialty Care (CSC) model of EP care (Heinssen et al., 2014), as executed in the University of California, Davis (UCD) Early Psychosis Program. This manuscript reports methodological details of the study and results pertaining to the first two study aims. For Aim 1, we sought to determine feasibility and acceptability of implementing a smartphone application as an add-on tool in EP care. Although feasibility has been established in individuals with chronic schizophrenia-spectrum diagnoses (Ben-Zeev et al., 2014, 2016a, 2016b; Palmier-Claus et al., 2012), first episode psychosis (Alvarez-Jimenez et al., 2013), and recent-onset schizophrenia (Schlosser et al., 2016), all these studies have been conducted independent of traditional outpatient care settings. To date, there are no data supporting feasibility as part of outpatient clinic care. For Aim 2, we sought to evaluate the validity of self-report symptom data collected via a smartphone application in EP. We have developed a self-report survey examining positive, negative, depressive/anxious, and cognitive symptoms based on our previous work implementing daily surveys in schizophrenia (Tully et al., 2014) that will be used to assess "early signs" of relapse in the current study.

We evaluated these aims using a longitudinal within-person design. Participants completed daily and weekly surveys examining mood, symptoms, medication adherence, and social behavior via a smartphone application for up to 14 months. Participants also completed monthly in–person psychosocial assessments using clinician-rated gold-standard measures. We hypothesized: 1) participants will show low dropout from smartphone-based assessment and high compliance with smartphone surveys; 2) self-report symptom data collected via smartphone will be highly correlated with gold-standard symptom measures.

2. Methods

2.1. Participants

To make results broadly applicable to individuals across the spectrum of psychosis, 76 EP individuals, comprising 64 individuals with Recent Onset Psychosis (ROP) and 12 Clinical High Risk (CHR) individuals receiving care at the UCD Early Psychosis Program, were included in the study. The UCD Early Psychosis Program comprises two clinics that provide services for both CHR and ROP individuals: EDAPT, a self-pay and/or insurance based clinic for individuals ages 12–40 regardless of county of residence, and SacEDAPT, a county contracted clinic supported by federal and state funds that provides care to Sacramento County residents ages 12–30 regardless of insurance status. Study inclusion criteria: age 13–30 years, English fluency, WASI (Wechsler, 1999) IQ above 70, no neurological disorders or current substance abuse/dependence per DSM-IV criteria. ROP participants are within three years of illness onset and have diagnoses of non-affective (i.e., schizophrenia, schizoaffective, schizophreniform, psychosis not otherwise specified) or affective psychosis (i.e., bipolar disorder with psychotic features; major depressive disorder with psychotic features) per the Structured Clinical Interview for DSM-IV Disorders (SCID) (First et al., 2002). CHR participants have no history of psychotic diagnoses

and demonstrate attenuated positive symptoms per the Structured Interview for Prodromal Syndromes (SIPS) (Miller et al., 2003). The UCD Institutional Review Board approved the study. Participants gave written informed consent and were paid for their participation.

2.2. Smartphone application

We utilized Ginger.io (Ginger.io, v. 3 2014), an mHealth software comprising a smartphone application ("app") and clinician Dashboard (see Fig. 1). The app can collect "active" data (i.e., self-report surveys sent to participants' smartphones at designated times/days) and "passive" data (i.e., data gathered from participants' smartphones without participant action) regarding phone calls made/received, SMS messages sent/received, and movement patterns (e.g., distance travelled in a day) based on Global Positioning System (GPS) data. Content of phone calls/SMS messages is never collected and specific location data is never explicitly analyzed. The app served as a data collection tool only; participants could not contact their treatment team, or review their data via the app. Instead, active and passive data for each participant were summarized on the Dashboard, a secure web-portal where clinicians reviewed participants' data, including daily and weekly survey responses, survey completion rates, and passive data summaries. Dashboard notifications appeared when participants did not complete surveys more than three days in a row, or when passive data were not being collected from a participants' phone. Clinicians also received Dashboard "alerts" when participants' responses were considered clinically significant, such as reporting a 2-point or more increase in any positive symptom (suspiciousness, auditory perceptual abnormalities, visual perceptual abnormalities) two days in a row, or responding "No, I did not take my meds today and I don't want to" two days in a row. Clinicians reported how these "alerts" informed their clinical/treatment decisions by responding in the Dashboard: 1) Was the patient in need of help or care? (yes, no, not sure); 2) If yes, what care did you provide? (Provided therapy/skills coaching/safety plan by phone, consulted with caregiver/treatment team, scheduled therapy appointment, scheduled medication appointment, referred to support services, referred to emergency services). Dashboard alerts were developed based on analysis of an initial 3 months of survey data from 39 participants and launched 6 months into data collection.

2.3. Clinicians

Clinicians (n = 8) included 1 Licensed Clinical Social Worker, 1 Licensed Marriage and Family Therapist (MFT), 2 Licensed Psychologists, 2 predoctoral psychology interns, 1 psychology practicum student, and 1 MFT intern. Clinicians were oriented to the app and Dashboard at study initiation, including how to navigate Dashboards, review and interpret survey data, and resolve Dashboard alerts. Clinicians were instructed to review survey responses with clients during regular treatment sessions, and to use Dashboard data/alerts to prompt contact with clients between sessions per clinical judgment/supervisors' recommendation.

2.4. Procedures

Study enrollment was open for 23 months. Participants were requested to complete a minimum of three monthly clinical assessments, but could choose to remain in the study for up to 14 calendar months (maximum funded data collection period per participant) or until data collection ended, whichever came first. Participants completed 1) daily surveys assessing mood, medication adherence, and social interactions, 2) weekly surveys assessing symptoms, sleep, and medication adherence via the app, as well as 3) monthly in-person psychosocial assessments with research staff. Daily surveys were sent at 5pm and expired at 11:55pm (local time). Weekly surveys were sent Sundays at 10am and expired Mondays at 11:55pm (local time). Participants received survey delivery notifications as well as reminder notifications two hours after survey delivery. Participants could choose to complete surveys at any point between survey delivery and expiration. Participants were paid $0.50 per daily and $1.50 per weekly survey (i.e., maximum $20 monthly payment). Daily and weekly surveys were developed from previous publications evaluating daily symptoms and psychosocial functioning in schizophrenia samples (Bauer et al., 2006, 2008; Hooker et al., 2014; Leibenluft et al., 1996; Tully et al., 2014). All daily and weekly survey items are provided in supplemental methods. Clinicians discussed survey responses during regular treatment sessions and informed study staff of any technical issues. Participants were informed in the consent, at study enrollment, and in the End User License Agreement of the app, that the app cannot be used to contact their clinician, doctor, or the clinic in the event of an emergency (e.g., medical emergency, suicidal ideation/attempt); participants (and parents/guardians) were reminded that they should call 9-1-1 in the event of an emergency. Safety issues were assessed as appropriate using standard clinic protocols (e.g., suicide risk assessment, safety planning) during regular in-person clinic appointments.

Weekly survey items (see supplemental methods) were summed to create composite scores for positive symptoms (3 items: suspiciousness item 4, auditory perceptual abnormalities item 8, visual perceptual abnormalities item 9; Cronbach's α = 0.75), negative symptoms (2 items: anhedonia item 5, avolition item 6; α = 0.79), depression/anxiety symptoms (2 items: sadness/depression item 1, worry/anxiety item 2; α = 0.77), and cognitive symptoms (2 items: confusion/distraction item 3, feeling overwhelmed item 7; α = 0.76). Passive data regarding number and length of SMS sent and received, number and duration of phone calls made and received, and distance travelled were also collected daily from participants' smartphones (Android devices only). If participants did not possess a smartphone, we provided an Android device for the duration of the study (see supplemental methods). We uninstalled Ginger.io from participants' phones at the final appointment.

To evaluate acceptability of using a smartphone application as part of EP outpatient care (Aim 1), participants completed self-report surveys at the end of the study evaluating satisfaction and perceived impact on clinical care.

To evaluate validity of symptom data gathered via smartphone (Aim 2), participants completed monthly symptom assessments using the Brief Psychiatric Rating Scale (BPRS) (Ventura et al., 1993). BPRS item scores were summed to create composite scores for positive symptoms (7 items: grandiosity, unusual thought content, bizarre behavior, disorientation, hallucinations, suspiciousness, conceptual disorganization; α = 0.61), negative symptoms (3 items: blunted affect, motor retardation, emotional withdrawal; α = 0.74), depression/anxiety (4 items: depression, anxiety, suicidality, guilt; α = 0.66), and agitation/mania (6 items: motor hyperactivity, excitement, distractibility, tension, uncooperativeness, mannerisms and posturing; α = 0.38) (Kopelowicz et al., 2008). B.A. level research staff conducted assessments, supervised by licensed clinical psychologists (TAN, LMT). Staff were trained to good-to-excellent reliability (ICCs > 0.75) via independent ratings of 4 videotaped interviews. Additional reliability analyses on 8 co-rated study assessments demonstrated continued good-to-excellent inter-rater reliability (all ICCs > 0.8).

See supplemental methods for details regarding additional measures that were gathered within the study to evaluate risk for relapse and recovery. These data, as well as daily surveys, passive data, and clinician responses to Dashboard Alerts will be reported in future publications.

2.5. Data analysis

Descriptive statistics were used to characterize feasibility and acceptability (Aim 1), including study enrollment, daily and weekly survey completion, and length of time participants were enrolled in the

Table 1
Baseline demographic and clinical characteristics of the participants (n = 76).

Baseline Demographic Characteristics	
Age (years), *mean* (*SD*)	18.8 (3.7)
Education (years)[a], *mean* (*SD*)	10.7 (2.4)
Parental Education (years)[b], *mean* (*SD*)	13.4 (2.5)
Male Gender, *n* (%)	50 (66%)
Race, *n* (%)	
African American	21 (28%)
Asian American	10 (13%)
Caucasian	41 (54%)
Native American	1 (1%)
Multiple	3 (4%)
Hispanic Ethnicity, *n* (%)	15 (20%)
Loaned Phone, *n* (%)	45 (59%)
Clinic[c], *n* (%)	
EDAPT	19 (25%)
SacEDAPT	52 (68%)
Outside Services	5 (7%)
Type of Phone, *n* (%)	
Android	58 (76%)
iPhone	18 (24%)
Baseline Clinical Characteristics	
Diagnosis, *n* (%)	
Schizophrenia spectrum disorder	49 (64%)
Mood disorder with psychotic features	15 (20%)
Clinical High Risk	12 (16%)
BPRS Aggression Mania[d], *mean* (*SD*)	10.4 (3.3)
BPRS Depression Anxiety, *mean* (*SD*)	10.7 (4.7)
BPRS Positive Symptoms[e], *mean* (*SD*)	14.0 (5.9)
BPRS Negative Symptoms[d], *mean* (*SD*)	5.8 (2.9)

Note: Due to rounding, percentages may not sum to 100. BPRS = Brief Psychiatric Rating Scale.
[a] Frequency Missing = 1.
[b] Frequency Missing = 8.
[c] 71 participants were receiving care at the University of California (UCD) Early Psychosis Program; 5 were receiving care from outside providers but had previously been enrolled in the UCD Early Psychosis Program and continued to engage in research.
[d] Frequency Missing = 2.
[e] Frequency Missing = 3.

app. Daily and weekly survey completion rates were calculated for each participant by summing the number of daily/weekly surveys completed and dividing the value by the total number of daily/weekly surveys they were sent during the entire period participants were enrolled in app (i.e., length of time in study). Other feasibility factors reported include: cost of providing smartphones, baseline symptom severity, and length of time in clinic at enrollment. We used Spearman rank correlation coefficient (ρ) to examine relationships between baseline symptom severity, length of time in study and survey completion rates. To evaluate acceptability, we examined participant ratings on satisfaction and perceived impact on clinical care.

Validity of symptom data collected via smartphone (Aim 2) was assessed by examining relationships between BPRS composite scores obtained by research staff at the end of each month and weekly survey composite scores collected via the app during the preceding 5 weeks (35 days) across three core symptom domains (positive symptoms, negative symptoms, depression/anxiety). Only data collected via smartphone 5 weeks prior to a BPRS assessment was included; if there was no smartphone data in the 5 weeks prior to a particular assessment, that assessment did not contribute data to analysis (e.g., if a participant had smartphone + BPRS data in months 1, 2, and 4, those data were included and the assessment conducted in month 3 was dropped). Because BPRS ratings reflect the most severe symptom in the month immediately prior to evaluation (Ventura et al., 1993), we used the highest weekly symptom composite score (i.e., the most severe weekly symptom rating) over the 5 weeks immediately prior to the monthly BPRS assessment as a predictor for the validity analysis. Participants with at least one monthly assessment (not including initial study enrollment) plus corresponding smartphone weekly symptom data in the 5 weeks prior to that assessment were included in validity analysis. Mixed-effects linear models (Laird and Ware, 1982) were used to characterize the longitudinal relationship between maximum weekly symptom data in each composite collected over the prior month and BPRS composite scores rated by research staff at month-end. This accounts for the correlated structure of the data due to repeated assessments over time and accommodates missing and unequally spaced observations. For each BPRS composite score, we first fitted a model with a fixed effect for the maximum weekly symptom composite score over the preceding 5 weeks, the linear effect of time (in months since the first monthly appointment), and random effects for person and time to account for within-individual repeated measures. The weekly symptoms coefficient can be interpreted as the average change in BPRS composite symptoms for a one-point change in weekly composite symptoms. In secondary models, we added terms for baseline BPRS composite symptom scores to evaluate whether baseline symptom severity influenced this association, and an interaction term between weekly symptoms and time to examine whether the association between BPRS symptoms and weekly survey symptoms increased or decreased over time.

All tests were two-sided (α = 0.05). Residual analyses and graphical diagnostics demonstrated model assumptions were adequately met. Analyses were implemented using PROC MIXED in SAS Version 9.4 (SAS, 2012).

3. Results

3.1. Feasibility

3.1.1. Study enrollment

Of 143 eligible individuals enrolled in the clinics, 41 (29%) declined to participate and 26 (18%) were non-responsive. Non-responsive individuals were also not engaging with the clinic, suggesting the lack of response was not specifically due to the nature of the research. Lack of consent from these individuals precluded analyses of group differences between those who declined and those who enrolled. Similarly, of the 41 individuals who declined to participate, 19 (46%) had declined all research opportunities associated with the clinic. Thus, only 22 (15%) individuals declined to participate explicitly because of the nature of this study (i.e., smartphone data collection).

The remaining 76 (53%) enrolled in the study. Participants remained in the study for an average of 183 days (*SD* = 88, Median = 174, Range = 3–433). Baseline positive [ρ = 0.08, p = 0.48], negative [ρ = - 0.01, p = 0.95], depression/anxiety [ρ = 0.02, p = 0.84], and agitation/mania [ρ = -0.22, p = 0.06] symptoms were not significantly associated with length of time in the study. See Table 1 for sample characteristics.

3.1.2. Provision of smartphones

We provided 45 (59%) participants with a smartphone; 38 (84%) of these participants were in our county-funded clinic (SacEDAPT). Nine (20%) of these participants required a replacement smartphone due to breakage/loss of the first device. Monthly cost of smartphone per participant was $34; average total cost of smartphone per participant was $361.18; the total cost of providing smartphones to all 45 participants was $16,253 (see Supplemental Table S1).

3.1.3. Survey completion

Weekly survey completion for the 76 enrolled participants was high (Mean = 77.3%, *SD* = 23.9%, Range = 0–100%). Only 9 participants had weekly survey completion rates lower than 50%, 2 of whom did not complete the first monthly assessment and were withdrawn from the study. Daily survey completion was also high (Mean = 69.0%, *SD* = 24.4%, Range = 5.3–100%). Only 16 participants had daily

Table 2
Parameter estimates for the linear mixed-effect models predicting BPRS symptoms using symptoms gathered via weekly smartphone self-report surveys.

Predictor Variable	Positive Symptoms		Negative Symptoms		Depression/Anxiety	
	Estimate (*SE*)	*p*-value	Estimate (*SE*)	*p*-value	Estimate (*SE*)	*p*-value
Model 1[a]						
Intercept	13.36 (0.44)	< 0.0001	5.95 (0.33)	< 0.0001	9.77 (0.41)	< 0.0001
Weekly Symptoms	0.56 (0.10)	< 0.0001	−0.04 (0.08)	0.60	0.58 (0.11)	< 0.0001
Time (months)	−0.23 (0.14)	0.10	0.09 (0.08)	0.26	−0.14 (0.12)	0.23
Model 2[b]						
Intercept	13.26 (0.35)	< 0.0001	5.91 (0.26)	< 0.0001	9.78 (0.35)	< 0.0001
Weekly Symptoms	0.42 (0.09)	< 0.0001	−0.07 (0.07)	0.29	0.44 (0.11)	< 0.0001
Time (months)	−0.26 (0.16)	0.12	0.09 (0.08)	0.26	−0.16 (0.12)	0.20
Baseline BPRS	0.39 (0.05)	< 0.0001	0.70 (0.09)	< 0.0001	0.42 (0.07)	< 0.0001
Model 3[c]						
Intercept	13.30 (0.35)	< 0.0001	5.86 (0.26)	< 0.0001	9.85 (0.35)	< 0.0001
Weekly Symptoms	0.52 (0.11)	< 0.0001	−0.17 (0.08)	0.048	0.59 (0.14)	< 0.0001
Time (months)	−0.33 (0.17)	0.053	0.15 (0.08)	0.08	−0.22 (0.13)	0.09
Time*Weekly Symptoms	−0.08 (0.05)	0.11	0.06 (0.03)	0.059	−0.08 (0.05)	0.12
Baseline BPRS	0.39 (0.05)	< 0.0001	0.71 (0.09)	< 0.0001	0.41 (0.07)	< 0.0001

Note: BPRS = Brief Psychiatric Rating Scale; SE = standard error. Time was centered at one month after the baseline visit, weekly symptoms were centered at the average before the first follow-up, and baseline BPRS symptoms were centered at the mean.

[a] From mixed-effect linear regression models fitted to the data with person as a random effect. Due to centering, the intercept can be interpreted as the average BPRS score at the first follow-up for a person who reported average weekly symptoms.

[b] From mixed-effect linear regression models fitted to the data with person and time as random effects. Due to centering, the intercept can be interpreted as the average BPRS score at the first follow-up for a person who reported average weekly symptoms and had average baseline BPRS symptoms.

[c] In these models, the fixed effect for weekly symptoms is interpreted as the effect of weekly symptoms at first follow-up; the time effect is interpreted as the effect of time for a person with average weekly symptoms.

survey completion rates lower than 50%, 2 of whom did not complete the first monthly assessment and were withdrawn from the study. Weekly [$\rho = 0.18$, $p = 0.12$], and daily [$\rho = 0.11$, $p = 0.35$] survey completion rates were not associated with length of time in the study, suggesting that participants' survey completion rates did not change significantly the longer they were in the study.

Baseline positive [$\rho = -0.07$, $p = 0.55$], depression/anxiety [$\rho = 0.05$, $p = 0.69$], and agitation/mania [$\rho = -0.12$, $p = 0.29$] symptoms showed no relationship to weekly survey completion rates. Severity of baseline negative [$\rho = -0.22$, $p = 0.06$] symptoms showed a small but non-significant correlation with weekly survey completion rate. Similar results were observed for daily survey completion; neither baseline positive [$\rho = -0.04$, $p = 0.76$], negative [$\rho = -0.12$, $p = 0.31$], depression/anxiety [$\rho = -0.09$, $p = 0.43$], nor agitation/mania [$\rho = -0.06$, $p = 0.64$] symptoms significantly related to daily survey completion. Length of time in clinic was not correlated with daily survey completion rate [$\rho = -0.08$, $p = 0.52$], weekly survey completion rate [$\rho = -0.04$, $p = 0.74$], and length of time in study [$\rho = -0.19$, $p = 0.10$]. This suggests that baseline symptom severity or length of time in clinic did not impede the feasibility of collecting weekly or daily self-report surveys via smartphone in EP.

3.1.4. Satisfaction surveys

Sixty participants completed satisfaction and perceived impact on clinical care surveys at the end of study enrollment (see Supplemental Tables S2 and S3). Fifty-eight (97%) participants reported that the app was easy to use (73% reported it was "extremely easy" to use; 23% reported it was "fairly easy" to use), 36 (61%) participants reported that the insights regarding their mood changes were interesting and accurate, and 47 (83%) reported that they would be open to continue using the app as part of their treatment services, if the app was available. Twenty-seven (46%) participants reported that the app helped them remember to take their medication and 24 (42%) reported that they were more motivated to manage their symptoms and medication routine after using the app.

In sum, half of eligible individuals were willing to enroll in the study, and remained in the study for 6 months on average. High survey completion rates (average 77% weekly; 69% daily) were not related symptom severity or length of time in treatment at the clinic, indicating that even symptomatic individuals early on in treatment are able and willing to engage in smartphone-based surveys as part of their treatment. Collectively, these results demonstrate that the majority of individuals receiving treatment for EP are interested and willing to use a smartphone app as part of their treatment.

3.2. Validity of smartphone symptom assessment

Of the 76 enrolled participants, 72 (95%) completed at least one monthly assessment (after initial enrollment assessment). Three (4%) completed 2 monthly assessments, 8 (11%) completed 3, 4 (5%) completed 4, 24 (32%) completed 5, 15 (20%) completed 6, 11 (14%) completed 7 or more monthly assessments (maximum 13).

Five participants did not provide any data for the validity analysis: 4 dropped out/withdrew from the study before completing any monthly assessments and 1 did not have any weekly surveys within any 5 weeks prior to any monthly assessment. One additional participant was excluded due to invalid survey data (participant reported randomly responding to survey questions throughout). Thus 70 participants were included in the validity analysis; 6 participants were not included (see Supplemental Table S4 for descriptive summaries of demographic and baseline clinical characteristics of the participants included and not included in the validity analyses).

See Table 2 and Fig. 2 for validity analyses summaries. After accounting for time in the study, weekly survey positive symptoms were significantly associated with BPRS positive symptoms ($\beta = 0.56$, $SE = 0.10$, $p < 0.001$). This relationship remained strong even after accounting for baseline BPRS positive symptom severity ($\beta = 0.42$, $SE = 0.09$, $p < 0.001$). Similarly, weekly survey depression/anxiety symptoms were significantly associated with BPRS depression/anxiety symptoms ($\beta = 0.58$, $SE = 0.11$, $p < 0.001$). This relationship was still significant after accounting for baseline BPRS depression/anxiety symptom severity ($\beta = 0.44$, $SE = 0.11$, $p < 0.001$). Weekly survey negative symptoms were not significantly associated with BPRS negative symptoms ($\beta = -0.04$, $SE = 0.08$, $p = 0.59$). After accounting for baseline symptoms, this association improved, but did not reach statistical significance ($\beta = -0.07$, SE = 0.07, $p = 0.29$). Even though the interactions between time and weekly surveys did not reach statistical significance in any of the three models ($p = 0.11$, 0.12, and

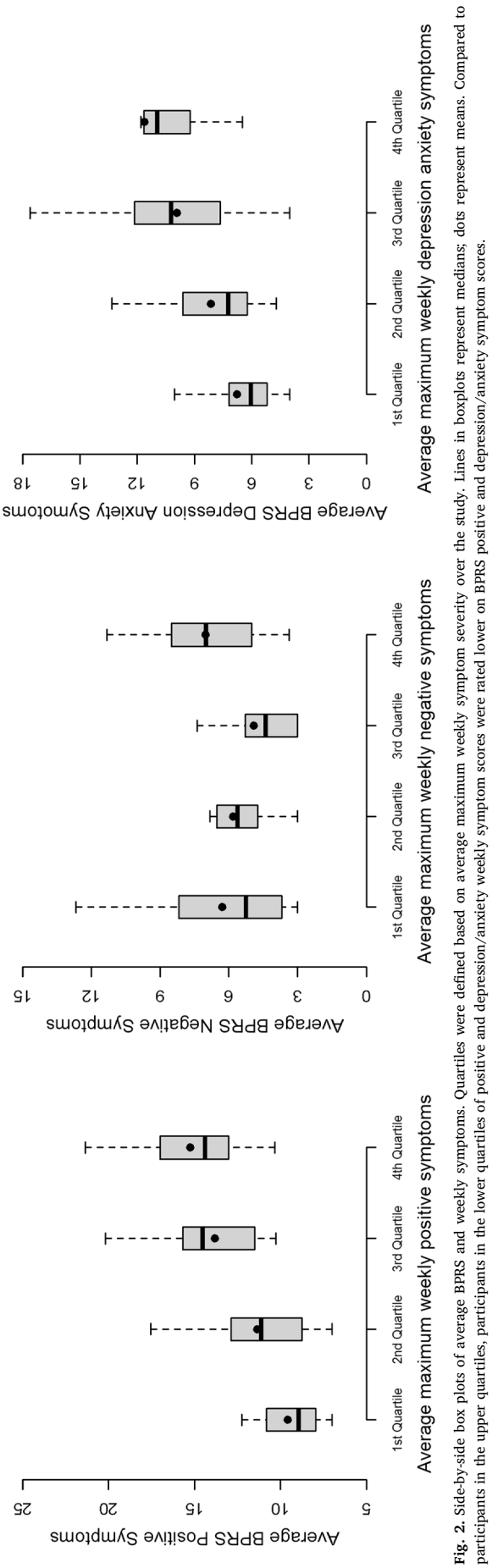

Fig. 2. Side-by-side box plots of average BPRS and weekly symptoms. Quartiles were defined based on average maximum weekly symptom severity over the study. Lines in boxplots represent medians; dots represent means. Compared to participants in the upper quartiles, participants in the lower quartiles of positive and depression/anxiety weekly symptom scores were rated lower on BPRS positive and depression/anxiety symptom scores.

0.059 respectively), they provided some evidence that the strength of associations may be stronger at first monthly assessment and gradually diminished over time. In sensitivity analyses, we restricted the validity analyses to the ROP (n = 59) participants. The results of the sensitivity analyses (see Supplemental Table S5) did not differ from the main validity analyses, demonstrating that the effects hold for individuals across the early psychosis spectrum.

Collectively, these data support the validity of smartphone-based assessment of symptoms in individuals with early psychosis. Specifically, results indicate that assessing positive and depression/anxiety symptoms using weekly self-report surveys via a smartphone app is comparable to symptom assessments obtained using a gold-standard clinician administered interview (i.e., the BPRS), regardless of baseline symptom severity, and may be a valid method of monitoring fluctuations in positive and depression/anxiety symptoms in EP populations.

4. Discussion

This study tested the implementation of a smartphone application combined with clinician Dashboard as an add-on tool in EP care. Here we report data pertaining to the feasibility and acceptability of the app in adolescents and young adults enrolled in treatment at the UCD Early Psychosis Program, as well as the validity of using the application for assessing symptoms in place of gold-standard clinician-rated assessments. Two main findings emerged.

First, results demonstrate that implementing a smartphone application as an add-on treatment tool in EP Coordinated Specialty Care is both feasible and acceptable. Fifty-three percent of eligible patients in the clinic enrolled in the study, indicating moderate-to-high interest in this new approach to care. Given 13% of potential participants declined all research opportunities at the clinic, simply having the smartphone app available to all individuals, independent of research, might result in higher enrollment. Participant retention was relatively high; 66% of enrolled participants remained in the study for at least 6 months. Survey completion rates remained high over the course of the study (weekly surveys: 77%; daily surveys: 69%). Participants endorsed high satisfaction levels and reported that they would be open to continue using the app if it was made available as part of their treatment. Of note, over 40% of participants indicated the app helped them remember to take their medication and increased motivation for symptom management and treatment engagement. This suggests that, for some individuals, simply tracking symptoms and medication adherence via an app may be an intervention in and of itself. Prior studies with similar designs report comparable retention (44–96%) and survey completion rates (58–88%) (Ben-Zeev et al., 2014, 2016a; Depp et al., 2015; Granholm et al., 2012; Hidalgo-Mazzei et al., 2016; Palmier-Claus et al., 2012; Wenze et al., 2016). Variations are likely explained by differences in the length of trial period, ranging from just 7 days (82% retention; 72% survey completion) (Palmier-Claus et al., 2012) to 6 months (79% retention; 65% survey completion) (Depp et al., 2015). Higher retention rates are also associated the inclusion of an intervention element in addition to symptom/mood assessment (Ben-Zeev et al., 2014), as well as participants' comfort using smartphone technology (Hidalgo-Mazzei et al., 2016). Future studies should include a control group to examine the relative clinical impact of in-app interventions and incorporation into treatment on participant engagement and retention.

Second, results show that weekly self-report assessment of positive and depression/anxiety symptoms via smartphone provides data comparable to that obtained via gold-standard clinician-rated assessments. This suggests that weekly assessment of positive and mood symptoms via smartphone may be a viable method of monitoring for signs of relapse/symptom exacerbation. Now that the construct validity of these weekly assessments has been established, future analyses will examine the predictive validity of weekly assessment via smartphone in predicting early signs of relapse. If, as we hypothesize, weekly assessments

of positive and mood symptoms via smartphone are predictive of impending relapse, this will indicate that weekly assessments (vs. more frequent assessments) may be sufficient for relapse prediction/prevention in real-world clinical settings, where more frequent assessments may not be feasible or may place undue burden on individuals who may be engaged in treatment for several years.

Weekly self-report negative symptom ratings were not associated with clinician ratings. These findings are consistent with prior studies conducted in chronic schizophrenia outpatient samples (Palmier-Claus et al., 2012), as well as ecological momentary assessment (EMA) studies (Ben-Zeev et al., 2012). Of note, Palmier-Claus et al. (2012) also reported relationships between self-report surveys via smartphone and gold-standard measures (in this case, the PANSS) of positive but not negative symptoms. Discrepancies between clinician-rated and self-report negative symptoms may partly be due to the limitations of the BPRS as an assessment of negative symptoms (Blanchard et al., 2011), as well as the largely observational nature of standard clinician-rated negative symptom ratings; observations in a single session may produce biased/inaccurate ratings. Additionally, the items identified as "early signs" and assessed in the negative symptom composite score of the weekly survey (anhedonia and avolition) may not have a strong relationship with the BPRS negative symptom composite (blunted affect, motor retardation, and emotional withdrawal), thereby impacting our ability to determine a meaningful association. Further, individuals may have difficulty observing these phenomena in themselves, possibly due to cognitive impairments impacting recall (Barch and Ceaser, 2012). Retrospective ratings are known to vary from in-the-moment assessment (Ben-Zeev et al., 2012), suggesting EMA of negative symptoms may be preferable. Recent findings indicate EMA of negative symptoms are more closely related to clinician ratings, but this relationship is moderated by working memory (Moran et al., 2017). Thus, although EMA methods may improve the validity of gathering self-report negative symptom ratings via smartphone, individuals with more severe working memory impairments may still struggle to accurately report their daily experiences. One suggestion, in addition to using EMA, is to incorporate family/caregivers to gather observational data via smartphone as well. Given the emphasis on family involvement in the Coordinated Specialty Care model (Heinssen et al., 2014), the addition of family/support persons to any add-on treatment tool is recommended regardless. Additionally, prior research indicates patients likely need more support to understand the relevance of their surveys to their daily lives, experiences, and outcomes (Palmier-Claus et al., 2013). Integrating regular structured support from treatment teams and family/support persons as part of the implementation of smartphone application treatment tools could assist patients in evaluating their negative symptoms and promote understanding of the direct association between monitoring symptoms and better outcomes.

This study has several limitations. First, although not a primary goal of this study, the lack of a control group renders it impossible to determine the relative clinical impact of incorporating symptom monitoring via smartphone into Coordinated Specialty Care. Second, because individuals that declined to participate did not consent to research, we are unable to assess clinical or demographic factors associated with not consenting to use smartphone technology as part of clinical care. Third, although the costs of implementation in the context of this research study were relatively low, the impact of the implementation on key treatment outcomes (e.g., relapse, hospitalizations etc.) remains unclear, and how those costs might change when implementing mHealth technology outside of a research setting is unknown. Whether the costs of providing smartphones and associated mHealth technology (i.e., software licensing costs, data management) are offset by reductions in other costs (e.g., fewer hospitalizations) is a key question facing behavioral mHealth research. Similarly, whether participants would have similar survey completion rates without monetary compensation is unknown. Future studies will need to evaluate the true cost of implementation in community based organizations (CBOs) that do not have the extensive research support (e.g., research funding, technical support) commonly available in university settings like the UCD Early Psychosis Program. Integration of smartphone based data collection into CBOs is a central challenge facing the mHealth movement. Successful adoption of mHealth technology requires extensive staff support for both the patients and providers, as well financial and technical resources that may not always be available (Holden and Karsh, 2010; Park and Chen, 2007).

5. Conclusion

These preliminary data regarding implementation of a smartphone app as an add-on tool in EP care are highly promising. The majority of patients willingly adopt the technology as part of their care, and symptom data gathered via smartphone appears to be a valid reflection of positive and depression/anxiety symptoms experienced over time. Future publications on this dataset set will investigate patient characteristics that are associated with better engagement in smartphone-related interventions, as well as the predictive power of symptom assessment via smartphone for identifying early signs of relapse and enabling early intervention and relapse prevention strategies.

Conflict of interest

None.

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Appendix A. Supplementary data

Supplemental data related to this article can be found at http://dx.doi.org/10.1016/j.jpsychires.2017.10.017.

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