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An Open Trial of a Smartphone-Assisted, Adjunctive Intervention to Improve Treatment Adherence in Bipolar Disorder

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Abstract

We evaluated the feasibility and acceptability of a novel, 12 week, adjunctive, smartphone-assisted intervention to improve treatment adherence in bipolar disorder (BD). Eight participants completed 4 in-person individual therapy sessions over the course of a month, followed by 60 days of twice-daily ecological momentary intervention (EMI) sessions, with a fifth in-person session after 30 days and a sixth in-person session after 60 days. Perceived credibility of the intervention and expectancy for change were adequate at baseline, and satisfaction on completion of the intervention was very high. Participants demonstrated good adherence to the intervention overall, including excellent adherence to the in-person component and fair adherence to the smartphone-facilitated component. Qualitative feedback revealed very high satisfaction with the in-person sessions and suggested a broad range of ways in which the EMI sessions were helpful. Participants also provided suggestions for improving the intervention, which primarily related to the structure and administration of the EMI (smartphone-administered) sessions. Although this study was not designed to evaluate treatment efficacy, most key outcome variables changed in the expected directions from pre- to post-treatment, and several variables changed significantly over the course of the in-person sessions or during the EMI phase. These findings add to the small but growing body of literature suggesting that EMIs are feasible and acceptable for use in populations with BD.

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Keywords

adherence; bipolar disorder; ecological momentary intervention; mobile health; smartphone

Treatment nonadherence is a significant concern in the management of bipolar disorder (BD). Most studies suggest that 40%–50% of individuals with BD are poorly adherent with their prescribed psychiatric medications^{1,2}; however, rates exceeding 75% have been reported.³ Although attendance at mental health appointments among patients with BD has been the focus of considerably less research, the literature suggests similar problems with adherence to appointments.^{4,5}

Treatment nonadherence is associated with worse outcomes and course of illness in BD. For example, patients who self-discontinue mood-stabilizing medications are at increased risk of suicide,⁶ and poor adherence with mood stabilizers is associated with a greater risk of hospitalization, relapse, use of emergency mental health care services, and higher levels of functional impairment.^{7–10} Treatment nonadherence is also associated with significant direct¹¹ and indirect¹² financial costs.

Adjunctive psychosocial interventions can improve treatment adherence in BD.^{13,14} Certain approaches, such as the use of interpersonal, cognitive-behavioral, and psychoeducational strategies, engaging patients in a detailed discussion of the nature of BD and effective treatment, and including interactional components between clients and therapists, may be especially effective in increasing adherence.¹⁵ Disorder-specific treatments have also been suggested as a key approach.¹⁶ Finally, interventions that target *potentially malleable* predictors of nonadherence (eg, locus of control regarding illness,¹⁷ quality of doctor–patient alliance,¹⁸ and negative beliefs about medications and negative attitudes towards treatment¹⁹) are likely to have more success. However, reviews of the available literature suggest that only about half of published interventions that have measured or specifically targeted adherence have found positive effects on this outcome (although most improved clinical outcomes^{15,16}). Furthermore, some researchers have noted that issues of cost and accessibility may preclude many patients with BD from even accessing efficacious interventions.²⁰

One potential strategy for improving adherence-related outcomes while also increasing treatment accessibility is to use an ecological momentary intervention²¹ (EMI) paradigm. EMIs use smartphones, tablets, remote sensors, and other mobile technology to deliver therapeutic content to clients in vivo. Potential advantages of EMIs include tailored timing or content of momentary interventions on the basis of patient needs or assessment responses, the chance for clients to practice new skills and apply new behaviors in real-life settings, and the provision of extra support between provider visits. With specific respect to improving treatment adherence, EMIs could potentially be used to monitor “real-time” adherence and neutralize risk factors for nonadherence before nonadherent behavior actually occurs. As such, researchers have begun assessing the efficacy of EMIs in adherence-focused interventions for populations struggling with a range of disorders (eg, HIV,²² kidney disease,²³ posttraumatic stress disorder,²⁴ schizophrenia²⁵). However, aside from our previous work, which laid the groundwork for the current intervention,²⁶ and a recent open

trial by Sajatovic and colleagues,²⁰ mobile technology has not been harnessed to address treatment nonadherence in BD. In our earlier open trial, we found that a brief EMI, delivered twice daily for 2 weeks via personal digital assistants, was feasible and acceptable to individuals with BD; depression scores decreased from pre- to post-intervention, and self-reported adherence was quite high throughout the study.²⁶ Sajatovic et al.²⁰ also tested a short (15-day) electronic intervention. Usability ratings were high and measures of adherence, symptoms, and treatment knowledge all changed in the direction of improvement.

Such findings provide preliminary support for the use of technology in addressing nonadherence among those with BD. However, both interventions were quite brief; interventions of a longer duration need to be examined, especially given the longer nature of other psychosocial treatments designed to improve adherence in BD.⁵ In addition, there is some evidence that EMIs are most effective when they entail a combination of face-to-face therapy and technology-delivered content (versus using mobile technology alone²⁷), and this is typically how mobile health interventions for populations with serious mental illness have been designed.²⁸ However, no published work of which we are aware has combined in-person content and EMI techniques in a tailored adherence intervention for BD. Importantly, available research suggests that mobile technology-assisted interventions (ie, interventions that combine in-person sessions with electronically-delivered therapeutic content) are feasible and acceptable in BD.^{29–31}

Given this framework, we developed an adjunctive, smartphone-assisted psychosocial intervention designed to improve treatment adherence in BD (“My Treatment” [MyT]). In this study, we report results of an open trial of the intervention, with a primary focus on feasibility and acceptability.

METHODS

Participants

Eight participants were recruited at a private psychiatric hospital from inpatient (n = 2), partial hospital (n = 3), and outpatient (n = 3) settings. Participants met the following inclusion criteria: 1) *Diagnostic and Statistical Manual of Mental Disorders* (DSM)-IV diagnosis of bipolar I or II disorder or bipolar disorder NOS, as determined by the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I³²); 2) score ≥ 11 on the Quick Inventory of Depressive Symptoms (QIDS-C³³) and/or ≥ 16 on the Clinician-Administered Rating Scale for Mania (CARS-M³⁴), corresponding to ratings of at least “moderate” depression and mania, respectively; 3) 18 to 65 years of age; 4) ability to speak, read, and understand English sufficiently well to complete study procedures; and 5) verbal report of comfort using the smartphones employed in this research study. Of note, we limited participation to adults (18–65 years old) because of the likelihood that adolescents, adults, and the elderly would use and relate to mobile health applications quite differently.³⁵ Exclusion criteria were: 1) psychotic symptoms (CARS-M psychosis subscale score ≥ 3 ³⁶) in outpatients, or at hospital discharge for inpatients and partial hospital patients; 2) schizophrenia or schizoaffective disorder; 3) alcohol or substance dependence within the past 12 months; 4) borderline or antisocial personality disorders diagnosed on the basis of

the SCID-II³⁷; 5) cognitive impairment sufficient to interfere with participation (Mini Mental State Examination [MMSE] score < 24^{38,39}); 6) acute suicidality at hospital discharge (for inpatients and partial hospital patients) or study enrollment (for outpatients), defined as a moderate or strong wish to die (Modified Scale for Suicidal Ideation [MSSI] Item 1⁴⁰), no or weak desire to live (MSSI Item 2), or any desire to make an active (MSSI Item 3) or passive (MSSI Item 4) suicide attempt.

Procedure

The Butler Hospital and Brown University Institutional Review Boards approved all study procedures. Using a Protected Health Information waiver, research staff screened electronic hospital charts. Staff approached patients who seemed to meet the inclusion criteria, gave them a brief overview of the study, and invited them to participate. We obtained written informed consent from those who chose to participate. We also secured releases of information to obtain information from, and share information with, participants' provider(s).

Bachelor's-level research assistants conducted in-person assessments at pretreatment (baseline), after the in-person sessions (at 1 month), and after the EMI sessions (posttreatment and after 3 months). Research assistants were formally trained in the use of all measures, achieved acceptable inter-rater reliability (kappas > 0.80) with faculty ratings before conducting independent assessments, and participated in ongoing monitoring of assessment recordings. Participants earned \$60 for completing baseline measures and \$30 for completing 1-month and 3-month measures.

On the basis of information obtained during the baseline assessment, the primary investigator (SJW) made a final determination as to participants' eligibility for the study. For those participants who were deemed eligible, the first therapy visit was scheduled for as soon as possible thereafter, typically within 1 week for outpatients, and within 1 week of discharge for inpatients and partial hospital patients.

MyT

MyT integrates psychoeducational and cognitive-behavioral principles, orientations that have been effective in increasing treatment adherence in unipolar depression^{41–44} and BD,¹⁵ and it involves sessions that are delivered both in-person and via smartphone. Participants completed 4 weekly individual therapy sessions with the primary investigator over the course of 1 month. They then completed 60 days of twice-daily (9:00 am and 9:00 pm, unless otherwise requested) EMI sessions administered via HTC Snap smartphones, using My Experience open source mobile data collection software. Participants completed a fifth in-person session 30 days after beginning the EMI sessions and a sixth in-person session after completing the EMI sessions. EMI sessions were scheduled twice daily to inquire about daily medications and appointments (morning sessions) and actual adherence behaviors (evening sessions). Participants were also able to access relevant material from the EMI sessions at any time. This “dose” and duration of therapy (ie, 6 in-person sessions for 50 minutes each, plus 120 EMI sessions for 2.5 minutes each, over 3 months) approximates the amount and timing of therapeutic contact that would be provided in a standard 12-week

course of psychotherapy, and approximately balances the amount of time spent in in-person and smartphone-administered sessions.

For scheduled EMI sessions, participants had up to 12 minutes to respond to a smartphone alarm, alerting them that it was time to complete a session, or they could delay a session by up to 30 minutes or skip a session entirely. Once a session was initiated, participants had a maximum of 1 minute to respond to each individual question. Participants received \$1 for each of the 120 scheduled momentary assessments they completed. Participants were not paid for unscheduled assessments. Smartphones were loaned to participants for the duration of the EMI portion of the study, and were set up so that they could only be used for study purposes. Study staff conducted brief telephone check-ins with participants after 15 days and again after 45 days to address any technical problems with the software or hardware, and to assess for participant safety. Because MyT was designed to be an adjunctive therapy, participants also continued with their usual outpatient care throughout the study procedures.

The overarching goal of the in-person sessions was to present participants with basic information that served as the framework and backdrop for the smartphone-delivered intervention. Research suggests that successful psychotherapeutic interventions in BD are interactive in nature^{45,46}; therefore, all of the in-person sessions involved role-plays, brainstorming exercises, or other collaborative experiences. For example, when discussing therapeutic alliance (session 4), the research clinician used role-playing exercises to help the participant practice raising concerns with his or her primary mental health care provider. Suicidal ideation was also assessed at each in-person session. The Health Beliefs Model,⁴⁷ which has been proposed as a useful framework for working with nonadherent patients, was used throughout (ie, sessions sought to address perceived benefits of adherence, barriers to adherence, susceptibility to illness, and severity of consequences). Table 1 presents a summary of the in-person session content.

During EMI sessions, smartphone software presented patients with a series of questions that assessed for symptoms that are common prodromes in BD (eg, mood, changes in sleep, psychomotor agitation or retardation, anxiety, and psychotic symptoms⁵³). The software also assessed for potential momentary risk factors for treatment nonadherence (eg, concerns about side effects, treatment alliance, and the need to take medications or to engage in mental health treatment^{51,52}). Mood was assessed on a 7-point Likert-type scale (1 = *most depressed ever*; 4 = *neutral*; 7 = *on top of the world*). Other symptoms and concerns were assessed in a simple yes/no format. On the basis of participants' responses, the software led them to brief, semi-individualized feedback messages. For example, if a participant indicated that he or she disagreed with his or her provider(s) about the need for treatment when he or she is feeling well, the participant received the following message:

People with bipolar disorder often feel this way, and may only take their medications or attend their mental health appointments now and then, whenever they feel they need to. But the way most treatments for this condition work is by helping to prevent future depressive or manic episodes, not just by treating your mood once you are already ill. In other words, keeping up with your treatment even

when you are feeling well helps prevent you from getting ill again. Some people think of it as investing in their future mental health.

Participants also received feedback on their reported mood and other symptoms. For example, potential coping strategies (including personalized strategies identified by participants and programmed into their devices) were presented when participants indicated depressed or elevated mood states, and the software calculated when mood shifted significantly to or from a depressed or elevated state and reflected this to participants. During morning sessions, participants were queried about treatment (medications and provider appointments) for that day; if a participant reported being uncertain about any aspect of that day's treatment, he or she received appropriate feedback (eg, to check his or her pill bottles or call the provider's office). During evening sessions, participants were asked about actual adherence behaviors (eg, doses taken, appointments attended) and they again received appropriate feedback (eg, suggestions for how to increase adherence on the following day, such as enlisting the aid of a specific, pre-identified support person, or using a planner or alarm). At each EMI session, the software queried participants about suicidal ideation and plans, calculated whether ideation had persisted from the previous session, and presented appropriate instructions to ensure participant safety. Specifically, if participants endorsed suicidal ideation and a plan for how to kill themselves, they were told to contact their provider or go to the nearest emergency room. If they reported low-grade suicidal ideation (ie, ideation with no plan) and this ideation persisted across more than one EMI session, this was reflected back to them and they were encouraged to contact a support person.

Measures

Diagnoses were established at baseline using the mood, substance use, and psychotic symptoms modules of the SCID-I³² and the antisocial and borderline personality disorder sections of the personality disorder modules of the SCID-II.³⁷ Cognitive impairment was evaluated using the MMSE.³⁸ We assessed BD symptoms using the QIDS-C,³³ CARS-M,³⁴ and MSSI.⁴⁰ Insight was assessed via the Mood Disorders Insight Scale (MDIS).⁵⁴ Treatment attitudes were evaluated using the Beliefs about Medicines Questionnaire (BMQ),⁵⁵ the Working Alliance Inventory-Client Short Form (WAI),⁵⁶ and the Multidimensional Health Locus of Control Scale, Form C (MHLC).⁵⁷ Expectancy for improvement due to MyT was evaluated using the 6-item, self-report Credibility and Expectancy Scale (CES),⁵⁸ and the scoring method described by Nock et al.⁵⁹ Participants also completed a measure concerning demographic characteristics at baseline.

We assessed adherence using an adapted version of the Medication Compliance Questionnaire (MCQ), and the Treatment Adherence Form (TAF), which have been used previously in BD treatment studies.^{60–62} Consistent with previous research,⁶² we operationalized medication nonadherence as the number of missed doses of the primary mood-stabilizing agent over each month of the study. On the TAF, participants reported missed mental health treatment appointments over each month of the study. At each assessment point, we mailed a blank MCQ and TAF to participants' identified primary mental health treatment providers, in an effort to obtain collateral information about adherence. However, response rate was extremely low (only one provider responded), so we

did not use these data. We also asked participants to bring in their pill bottles to each assessment to complete pill counts. For those who forgot, we gave them a blank form to complete at home and mail back. Six participants completed pill counts at baseline, 4 did so at 1 month, and 3 did so at 3 months. For those who completed pill counts, data were consistent with responses on the MCQ. Therefore, we used the MCQ (for which we had no missing data) as our measure of medication adherence.

At the 1-month and 3-month assessments, participants again completed the QIDS-C, CARS-M, MSSI, MDIS, BMQ, WAI, MHLC, MCQ, and TAF. At the 3-month timepoint, we assessed satisfaction with MyT, using the Client Satisfaction Questionnaire (CSQ-8)⁶³ and a series of 5-point Likert-type scales. Finally, participants were given an opportunity to provide open-ended feedback on the intervention in an interview with a research assistant.

Overview of Statistical Procedures

We used SPSS 22.0 and HLM 6.01 for all analyses. Hierarchical linear modeling (HLM; HLM 6.01) and paired-samples *t* tests (SPSS 22.0) were used to explore change in outcome variables over time. HLM accounted for the nested structure of our data and handled missing data at level 1 using listwise deletion.⁶⁴ We also used HLM to estimate means and standard deviations of variables from the EMI sessions (ie, “momentary variables,” such as mood and time delay in responding to smartphone prompts), and change in momentary variables over time.

RESULTS

Participant Flow and Descriptive Statistics

Research staff approached a total of 29 patients regarding participation in the study. Three declined for logistical reasons (eg, lived too far from the hospital), 9 declined for other or unknown reasons, and 5 expressed interest, but were subsequently discharged and lost to follow-up. The remaining 12 individuals provided consent and began baseline assessments. Of these 12 participants, 3 were deemed ineligible (current substance use disorder and antisocial personality disorder, *n* = 1; cognitive impairment, *n* = 1; no BD, *n* = 1), and 1 was lost to follow-up before completing baseline measures. This resulted in our final sample of 8 participants.

Participants (BD-I, *n* = 5; BD-II, *n* = 1; BD NOS, *n* = 2) were recruited from inpatient (*n* = 2), partial hospital (*n* = 3), and outpatient (*n* = 3) settings. All of the participants were experiencing depressive episodes, and none was rapid cycling. Five participants were female and 3 were male. Average age at study enrollment was 44 years (*SD* = 11.58 yr). All of the participants identified as white, and 1 also identified as Hispanic. On average, participants had completed 16 years of education (*SD* = 2.31). Three were married, 4 were divorced, and 1 was single. Seven (87.5%) had a household income less than \$50,000. Participants reported an average of 2 lifetime inpatient psychiatric hospitalizations (*SD* = 1.93) and 2.25 psychiatric partial hospitalizations (*SD* = 1.39). Five participants reported having attempted suicide. The average number of attempts was 1.13 (*SD* = 1.13). On average, participants were prescribed 3.25 (*SD* = 0.89) psychiatric medications at baseline and attended 1 (*SD* =

0.51) mental health appointment per week. Three participants received medication treatment only, and 5 received medication plus therapy (modalities included individual therapy and family therapy). Mean baseline QIDS-C and CARS-M scores were 15.25 (SD = 3.20; “moderate”) and 7.25 (SD = 4.33; “questionable”), respectively. Participants reported missing an average of 17.5% (SD = 24.35%) of their scheduled mental health appointments and 1.13 (SD = 0.83) doses of their primary mood-stabilizing agent in the past month.

On average, participants took 14.25 (SD = 20.07) minutes to respond to alarms and spent 2.90 (SD = 1.86) minutes on EMI sessions. Time delay in responding to alarms did not change as the study progressed ($b_{10} = 10.22$, SE = 5.57, $P = 0.11$). Similarly, participants spent the same amount of time on EMI sessions over the course of the study ($b_{10} = -0.59$, SE = 0.36, $P = 0.14$). Participants were no more likely to skip or respond to scheduled EMI sessions as the study progressed ($b_{10} = 0.00$, SE = 0.00, $P = 0.75$). However, they were slightly less likely to initiate unscheduled assessments as the study progressed ($b_{10} = -0.01$, SE = 0.00, $P = 0.01$). All participants completed all in-person assessments (baseline, 1-month, 3-months).

Feasibility and Acceptability

At baseline, the average CES total score was 42.13 (SD = 9.64) out of a possible total of 54. The credibility subscale score was 22.38 (SD = 6.30) and the expectancy for change subscale score was 19.75 (SD = 4.17), both out of a possible total of 27. All participants completed all in-person sessions and returned all smartphones undamaged. Participants completed an average of 80.88 (SD = 26.43) EMI sessions overall, and an average of 37.75 (63%; SD = 12.23) morning sessions and 32 (53%; SD = 16.95) evening sessions. This corresponds to an average of 58% of scheduled EMI sessions. They completed an average of 11.13 (SD = 8.89) unscheduled sessions. Number of sessions completed was not associated with initial manic or depressive symptoms or baseline levels of adherence (all $P > 0.10$). At posttreatment (3-month) follow-up, the average CSQ-8 total score was 31 (SD = 1.31), out of a possible total of 32. On 5-point Likert-type scales (1 = *very dissatisfied*, 5 = *very satisfied*), the average rating was 5 for overall satisfaction (SD = 0), 5 for satisfaction with the in-person sessions (SD = 0), and 4.63 for satisfaction with the EMI sessions (SD = 0.52). The average rating was 4.88 for perceived helpfulness of the intervention (SD = 0.35; 1 = *not at all helpful*, 5 = *extremely helpful*) and 4.63 for smartphone ease of use (SD = 0.74; 1 = *not at all user-friendly*, 5 = *extremely user-friendly*). Likert scale ratings were unrelated to initial manic or depressive symptoms or baseline levels of adherence (all $P > 0.10$).

Qualitative feedback about MyT is summarized in Table 2. Feedback was generally positive, but some suggestions for improvement were also noted (eg, regarding structure and administration of the EMI sessions). One participant experienced technical problems with the smartphone. Participants indicated universal satisfaction with the in-person sessions. One participant stated she felt this portion of the intervention was most helpful. However, all participants reported that EMI sessions were useful in at least 1 important way (eg, as a source of extra support, increasing insight, or improving adherence). One participant volunteered that she looked forward to the EMI sessions, and another indicated, “I’m sad to be stopping!”

Preliminary Evidence for Efficacy

As noted, our primary goals were to evaluate the feasibility and acceptability of MyT; the study was not designed or powered to detect treatment effects. However, we examined relevant variables and conducted exploratory analyses to evaluate preliminary evidence for MyT's efficacy. First, we examined average levels of momentary outcome variables, as assessed during the 60-day EMI portion of the study, and whether these variables changed over time. The average momentary mood rating was 3.96 (SD = 1.06) and the average number of treatment-related concerns per EMI session was 1.38 (SD = 0.86). Participants endorsed suicidal ideation on 5% (SD = 22%) of occasions. During morning assessments, participants reported knowing what medications to take for that day, at what doses, and at what times 99% of the time (SD = 10%), and what appointments they had, at what times 100% of the time. During evening assessments, participants reported having missed medication doses 12% of the time (SD = 27%). Only 2 participants reported missing any mental health appointments (1 appointment each). None of these variables changed over the course of the EMI portion of MyT (all $P > 0.10$).

Next, we used HLM to explore changes in the outcome variables that were assessed in person at baseline, 1-month, and 3-month time points. None of these variables (ie, QIDS-C, CARS-M, MSSI, MDIS, BMQ, WAI, MHLC, MCQ, or TAF) changed significantly (all $P > 0.10$). However, most variables changed in the expected direction, sometimes to a considerable degree. Specifically, both depression scores and missed medication doses decreased by 22%, missed appointments decreased by 71%, and suicidal ideation decreased by 100%. Insight and working alliance increased slightly (by 1% and 3%, respectively). See Table 3.

Finally, because MyT was delivered in 2 somewhat distinct phases (ie, the 30-day, in-person phase, and the 60-day, primarily EMI phase), we used paired-samples t-tests to explore change in these same outcomes from baseline to 1-month, and from 1-month to 3-months (corresponding to the in-person and EMI phases, respectively). From baseline to 1-month, scores on the MHLC "internal attributions" subscale decreased significantly ($t(7) = 3.05$, $P = 0.02$; $d = 0.73$), scores on the MDIS "attributions to illness" subscale decreased marginally ($t(7) = 2.02$, $P = 0.08$; $d = 0.79$), and scores on the BMQ "concerns about medications" subscale increased significantly ($t(7) = -3.05$, $P = 0.02$; $d = 0.56$). From 1-month to 3-months, insight increased significantly ($t(7) = -2.46$, $P = 0.04$; $d = 0.71$) and missed medication doses decreased marginally ($t(7) = 1.93$, $P = 0.10$; $d = 0.71$). See Table 3. No other significant differences were found.

DISCUSSION

Results from the current open trial provide initial evidence of feasibility, acceptability, and efficacy of the MyT intervention in BD populations. Perceived credibility of the intervention and expectancy for change were adequate at baseline, and satisfaction upon completion of the intervention was very high. Participants demonstrated good adherence to the intervention overall, including excellent adherence to the in-person component and fair adherence to the smartphone-facilitated component. Importantly, self-reported adherence to outside treatment (ie, medication and mental health appointments) during the study period was relatively high.

Qualitative feedback revealed very high satisfaction with the in-person sessions, and the feedback suggested a broad range of ways in which the EMI sessions were helpful, most notably as a way to increase adherence and insight, and stay connected between provider visits. Participants also provided some helpful negative feedback and suggestions, which primarily related to the structure and administration of the smartphone-administered sessions. Although this study was not designed to test treatment efficacy, most key outcome variables changed in the expected directions from pre- to post-treatment, and several variables changed significantly over the course of the in-person sessions (ie, the first month) or during the EMI phase (ie, months 2 and 3).

These encouraging findings fit with a small but rapidly growing body of literature demonstrating the feasibility and acceptability of EMIs^{20,26,29–31,65} and other technology-assisted interventions⁶⁶ in populations with BD. Although mood symptoms, poor insight, distractibility, and other core features of BD might be expected to preclude the ability to complete EMI sessions or other therapeutic tasks outside of the mental health care setting, the current findings suggest that such concerns may be unfounded. That said, rate of compliance with the EMI portion of MyT (58%) was considerably lower in this study than in our previous pilot work (92%),²⁶ and lower than in other published work using EMIs in BD (87%²⁹; 78%³¹; 65%³⁰). One possible reason may be that the EMI portion of MyT lasted longer than in our previous work (60 versus 14 days), and EMI sessions took longer (2.90 versus 1.85 minutes). In addition, MyT participants also completed in-person sessions (which came first and which received higher satisfaction ratings), which may have negatively impacted EMI adherence. Of note, EMI adherence in a previously published intervention for BD that was structured similarly to MyT (4 in-person sessions plus 2 EMI sessions per day for 10 weeks³⁰) was only slightly higher than in the current study (65% versus 58%).

Regardless of the reasons, addressing participant feedback is likely to increase adherence, perceived credibility, expectancy for change, and satisfaction in future iterations of MyT. Most importantly, future trials should consider using software that permits participants to schedule their own EMI sessions, that allows greater variation in smartphone-delivered feedback and responses, and that can run on participants' own mobile devices, if they have them. The incorporation of more sophisticated technology, such as motion or passive sensors, physiological monitors, and real-time or asynchronous assessments that prompt additional intervention, is becoming increasingly feasible and should also be considered in the future.^{67–69}

As noted, we were encouraged to find that most of our key outcome variables changed in the expected directions over the course of the study period. Further, several outcomes changed significantly over the course of the in-person or the smartphone-delivered portions of MyT. The changes that occurred during the EMI sessions (increased insight and marginally increased medication adherence) are encouraging and invite replication in future trials. The changes that occurred during the in-person sessions (decreased internal locus of control for mental health and increased concerns about medication) were, at first glance, unexpected. However, examination of specific items that make up these subscales suggests that the observed changes may reflect participants' attainment of a more sophisticated, informed

understanding of BD and related treatment issues. For example, one of the items on the MHLC “internal attributions” subscale is, “I deserve the credit when my BD improves and the blame when it gets worse.” Although MyT encouraged participants to think about what they could control in terms of their symptoms, course of illness, and treatment, in-person sessions also highlighted the role that providers, medication choice, access to care, and other factors play in the course of BD. Similarly, one item from the BMQ “concerns about medications” subscale reads, “I sometimes worry about the long term effects of my medicines.” As noted, in-person session 3 is devoted primarily to discussing typical side effects of BD medications, and consideration of the shortcomings of various existing treatments (both pharmacological and psychological) is discussed throughout MyT.

Limitations to the present study should not be overlooked. Our sample size was small and demographically restricted, and all participants were depressed. This last point is noteworthy, as adherence issues differ between depressed and (hypo)manic phases of BD (eg, insight varies, reasons for nonadherence are different, and treatments differ).⁵ Further, we did not select for poor treatment adherence. Although participants reported difficulties adhering to treatment at baseline, the level of nonadherence was not as high as has been documented in some studies.^{70,71} Results may not generalize to those in (hypo)manic states, individuals with higher levels of nonadherence, or more diverse populations. We included participants with a range of BD diagnoses, we recruited from multiple settings reflecting various levels of care, and participants’ community treatment varied widely, all of which may have obscured treatment effects. Importantly, given the pilot nature of this work, participants were compensated for completing EMI sessions, and we excluded patients with comorbid substance use disorders or cognitive impairment (conditions which are common in BD and which are linked with poor adherence, but which would likely necessitate tailored approaches that were beyond the scope of this pilot trial^{62,72}). The rate of EMI session completion might be lower if participants were not paid for completing sessions, or if participants with substance use disorders or cognitive impairment were included. The lack of an objective measure of adherence is another limitation; although self-report measures have been shown to be reliable,¹⁴ a multimodal assessment strategy is recommended whenever possible.^{15,73} We did attempt to procure provider ratings of participants’ adherence, but the response rate was so low as to render these data unusable. Future work should consider ways to boost provider compliance with requests for such information, make it easier for participants to complete pill counts, or include alternate supplemental ways to measure adherence (eg, electronic pill bottles, pharmacy records, or serum drug levels). In addition to testing MyT in a fully powered, randomized controlled trial, future work should also aim to determine which components of the intervention (in-person versus EMI sessions) are most efficacious; it is possible that the high acceptability and apparent positive benefits of MyT could have been accentuated by or largely due to the 4 in-person sessions, rather than the EMI sessions.

In sum, the current open trial yields further support to the use of mobile technology-assisted interventions in treating BD in general, and in addressing nonadherence specifically. Given the numerous treatment barriers⁷⁴ and infrequent provider contact that typically characterize this population,^{75,76} these findings are encouraging. EMIs such as MyT can potentially circumvent some common barriers to treatment, such as lack of transportation, stigma, and

financial constraints, and provide additional therapeutic contact in a low-cost, easily disseminated way. Future research is needed to examine whether MyT is efficacious in increasing treatment adherence, decreasing BD symptoms, and increasing functioning.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table 1

Summary of the Content of In-Person Sessions

Session	Topic	Summary
1	Overview of BD; education about treatment	Psychosocial and psychoeducational interventions in mood disorders have effected positive change on adherence by providing patients with information about their diagnosis and the ways in which treatment works. ^{41,43,48} Patients are also encouraged to discuss perceived costs and benefits of adherence.
2	Barriers to adherence; challenging thoughts/beliefs about medications and illness	Nonadherence may be addressed by discussing relevant barriers and using cognitive and behavioral strategies to challenge maladaptive thoughts regarding medication and illness. ^{49,50} Patients also discussed perceived susceptibility to illness and consequences of depressive and (hypo)manic relapse.
3	Side effects; coping strategies	Side effects are the most commonly cited reason for nonadherence in BD. ⁵¹ Teaching coping strategies to deal with side effects and other discomforts of mood disorders may improve adherence rates. ^{41,44}
4	The therapeutic relationship; training in the use of the smartphone	Given that a positive therapeutic alliance is associated with improved adherence rates in BD, attention was devoted to participants' perceived alliance with their primary provider(s) and ways to improve that alliance. ⁵² At this visit, participants were also trained in the use of the smartphone for the next portion of the study, and they received a short, printed guidebook.
5	Review of material presented in sessions 1–4	We also assessed for safety, asked about any problems with the smartphone, and uploaded the first 30 days of data.
6	Summary and wrap-up	Participants returned smartphones at this session.

Table 2

Qualitative Feedback on the Intervention

In-person sessions	
Theme (# endorsing theme)	Examples
Satisfaction (8)	“I felt understood.” “Even more in-person sessions would be good.”
EMI sessions: Positive Feedback	
Theme (# endorsing theme)	Examples
Ease of use (7)	“Very easy to use!” “No [negative] impact on my daily life. It was easy.”
Improved adherence (5)	“I’ve been taking my medications more regularly since I started to carry [the smartphone].” “The reminders helped me remember to take my meds.”
Source of extra support (4)	“It felt there was always someone there to listen.” “It was like a link.” “I felt connected.”
Increased insight (3)	“It made me more aware of how I was feeling.” “Made [me] think about [my] mood and [it was] helpful to track how [my] moods changed.
Helped maintain a daily schedule (2)	“It was very helpful, especially in organizing my day.” “It’s like you have an appointment with yourself!”
Reminder to seek support (1)	“It helped me seek help.”
Appreciating feedback (1)	“I liked the personalized messages.”
Reframed thinking (1)	“[The smartphone] reminds you that you have a lot of control over [bipolar disorder].”
Integration with in-person component (1)	“Felt like an appropriate extension of the in-person sessions.”
EMI sessions: Negative feedback	
Theme (# endorsing theme)	Examples
Desire for flexibility in timing (5)	“If I could schedule the time of the sessions every day it would have been easier.”
Logistical & technical suggestions (3)	“Have [the phone] attach to your belt.” “Eventually have [the program] on your own phone.” “Too many items on the [smartphone] instruction sheet.”
Desire for more variation in questions and feedback (1)	“More change from one assessment to the next.”
Frustration with question anchors (1)	“[I was] frustrated with the anchors. Felt like I was unable to express the full range of [my] current feelings.”

Table 3

Values of key outcome variables at the three assessment time points

Variable	Baseline <i>M (SD)</i>	1-month <i>M (SD)</i>	3-month <i>M (SD)</i>
QIDS-C	15.25 (3.20)	11.63 (4.98)	11.88 (5.08)
CARS-M	7.25 (4.33)	6.38 (6.35)	7.50 (5.66)
MSSI (suicidal ideation, item 1)	0.50 (0.76)	1.38 (2.07)	0 (0)
TAF (% appointments missed, past month)	17.50 (24.35)	4.13 (11.67)	5.00 (9.26)
MCQ (# missed doses, past month)	1.13 (0.83)	1.50 (1.07) ^b	0.88 (0.64) ^b
MHLC			
Internal attributions	25.63 (2.92) ^a	22.50(5.26) ^a	25.25 (6.45)
Chance	15.00 (7.31)	14.00 (6.87)	14.88 (7.97)
Doctors	15.38 (2.88)	15.38 (1.92)	15.75 (2.82)
Others	10.13 (2.59)	10.38 (3.62)	9.50 (4.69)
BMQ			
Necessity of medication	8.13 (3.04)	8.50 (2.83)	9.63 (3.42)
Concerns about medications	16.63 (2.50) ^a	18.25 (3.28) ^a	16.63 (4.27)
Harm caused by medications	11.50 (2.78)	12.50 (2.45)	12.75 (1.83)
Overuse of medications	15.50 (2.78)	15.88 (2.30)	15.88 (2.53)
WAI			
Task	22.50 (4.50)	23.63 (6.14)	22.88 (6.06)
Bond	24.50 (4.34)	24.25 (4.53)	25.25 (3.06)
Goal	22.00 (3.85)	22.88 (6.20)	23.25 (5.04)
Total	69.00 (11.51)	70.75 (16.57)	71.38 (13.93)
MDIS			
Awareness of illness	3.69 (0.46)	3.81 (0.37)	3.88 (0.23)
Attributions for symptoms	3.83 (0.47) ^b	3.38 (0.68) ^b	3.67 (0.62)
Perceived need for treatment	3.88 (0.35)	3.92 (0.24)	4.00 (0)
Total	11.40 (0.82)	11.11 (0.65) ^a	11.54 (0.58) ^a

QIDS-C, Quick Inventory of Depressive Symptoms-Clinician-Rated; CARS-M, Clinician-Administered Rating Scale for Mania; MSSI, Modified Scale for Suicidal Ideation; TAF, Treatment Adherence Form; MCQ, Medication Compliance Questionnaire; MHLC, Mental Health Locus of Control Scale; BMQ, Beliefs About Medications Questionnaire; WAI, Working Alliance Inventory; MDIS, Mood Disorders Insight Scale.

^aSignificant difference ($P < 0.05$).

^bMarginally significant difference ($P < 0.10$).