Supplementary Online Content

Place S, Blanch-Hartigan D, Smith V, Erb J, Marci CD, Ahern DK. Effect of a mobile monitoring system vs usual care on depression symptoms and psychological health: a randomized clinical trial. *JAMA Netw Open*. 2020;3(1):e1919403. doi:10.1001/jamanetworkopen.2019.19403

This supplementary material has been provided by the authors to give readers additional information about their work.

eMethods. Supplemental Methodological Descriptions

Description of enrollment, informed consent and follow-up

Screening involved 213 potential participants across two clinics. iPhone users (n=110) were excluded because the iPhone operating system did not allow the mobile monitoring system the same capabilities to access smartphone metadata and therefore the application could not offer feedback on 3 of the 4 models to patients and clinicians. Sixty-eight patients were randomized for the study (Figure 1).

Patients were enrolled in the study from February 2016 to June 2017. Six months after enrollment the mobile sensing application shut off and was automatically removed from the user's Android smartphone device. The study had a scheduled end date on August 31, 2017 when the smartphone would stop data collection and be removed from the devices of all patients. Even knowing this end date, enrollment contiued past February 2017. This revision to the enrollment period was made to try and increase the sample size and was in response to challenges in staff turnover and enrollment at the study clinics. This change was submitted and approved by the NIH SBIR program officer in April 2017. Continuing enrollment past February 2017 meant that not all randomized patients received the full 6-month intervention. There were 13 patients (6 in usual care and 7 in the intervention) who had the application on their phone for less than 150 days when the study ended on August 31, 2017 and were not included in this analysis.

After 6 months, patients were contacted by phone to set up a time to come into the clinic to complete the follow-up survey. If possible, this was scheduled for an upcoming appointment. If patients could not fill out the follow-up survey in the clinic, or no-showed for their scheduled appointment, they could complete their follow-up survey by telephone. The follow-up survey was completed an average of 196 days (SD=46) after the baseline survey. Forty-nine patients completed the follow-up survey within 30 days of the mobile monitoring system being shut off on their phones. Patients who could not be reached for follow-up after three attempts were considered lost to follow-up. Two patients were lost to follow up and did not complete the follow-up survey. Fifty-three patients are included in the final analysis.

No patients dropped out of the study. We attribute the low attrition rates to the low study burden, ease of use of the application and highly engaged clinical and research teams.

Description of protocol and informed consent

New and existing patients to the clinics were recruited based on clinical presentation and interest in study participation. Brochures with study information were placed in clinic waiting rooms and provided to clinicians as advertisements. Once patients expressed interest in the study, they were screened for eligibility. Inclusion criteria included being the primary user of a smartphone with an active voice and data plan, age 18-64, and the ability to read, write and speak conversational English. Exclusion criteria included cognitive impairment impeding adherence to study protocol, active suicidal or homicidal thoughts, and symptoms of psychosis.

Patients provided informed consent face-to-face on site at the clinic or by phone. After a potential participant had received clinician approval and expressed interest in the study, they were given a copy of the IRB-approved brochures about the study and/or a brief overview (5 minutes) with the research assistant. They were given time to review the consent form. The patient then had the chance to ask the study staff any questions. If the patient agreed to participate, they could sign the form and return the signature sheet to study staff either as a hard copy or as a scanned copy through email. Research staff also signed and sent the patients a final copy of the Consent Form with both signatures. A second phone call or an in-person visit was then scheduled with research staff after a signed copy of the patient's consent form was received to administer the self-report measures to the patient and instruct them on usage of the mobile application.

Patients were randomized to either a control group (usual care) or the intervention group (usual care plus the mobile monitoring system). Patients assigned to the intervention group downloaded the mobile monitoring application from the app store onto their personal Android smartphones and were provided with a unique and deidentified username and password for access. At the end of the study period, the application was automatically removed from patients' smartphones and patients were re-contacted by study staff to complete exit surveys. These could also be completed either in person or over the phone.

Patients were compensated for participation in the study. Compensation was not dependent on study group assignment. Participation in each month of the study was compensated at $20. If patients complete all 6 months of the study, they were compensated with a bonus of $30. Thus, the total possible compensation for a participant was $150. Patients were paid by check.

Description of usual care and the mobile monitoring system

Usual care was defined in the original grant submission and clinical protocol as standard best practices of care provided by the participating clinic. This included clinically accepted psychopharmacology and/or psychotherapy interventions. The treating clinicians for control patients receiving usual care did not receive any feedback through the study period. The current patient population was a general behavioral health population receiving treatment by a clinical social worker with a supervising psychiatrist in an integrated primary care and behavioral health clinic. The treatments were diagnosis and treatment agnostic. We did not track or compare the details of the usual care received by patients in either arm of this trial.

After consent, patients randomized to the intervention group downloaded the mobile monitoring system patient application from the app store onto their personal smartphones. A clinician or research associate provided the patient with a unique and de-identified registration token that allowed patients to log in to the app and set a password. Patients randomized to the usual care control condition did not download the application on their phones. Both the usual care group and the intervention group were Android phone users.

There are three components to the mobile monitoring system: a smartphone application (app) for patients, the cloud-based artificial intelligence (AI) processing and the clinician dashboard (CompanionMx, Inc.). The app collects vocal features from short, audio diary recordings. The app also passively measures patients' behavioral patterns through a combination of call, text and location patterns. The app does not collect or analyze the content of phone calls or messages.

The cloud-based AI analyzes the vocal features and smartphone use data to compute four clinically relevant indicators of mental health: depressed mood, fatigue, social isolation, and diminished interest. The models used in the analyses are based on previously published data.[1] Feedback on these indicators are shared with patients via the app and clinicians via the dashboard. The dashboard provides clinicians with a secure and confidential view of current and historical indicators over time. The mobile monitoring system does not provide clinical or medical advice.

Patients interacted with the application in two ways. They were able to record audio check-ins via the application and also view line and bar charts of the four model scores over time. The feedback provided was a model score of symptoms of depression and PTSD (eFigure 1). Patients saw this as four indicators: "mood" "out and about" "socially connected" and "energized." No additional feedback to the patient on this application was provided. A screenshot of the patient-facing application is included below.

The mobile monitoring system collected the same type of passive information for all patients. Patients, however, could vary in how much they interacted with the application. Patients chose how many audio recordings to leave on the application and how often to view and track their scores. Differences in application usage by patients were not assessed in the present study.

In addition to the patient-facing application, clinicians were also able to monitor their patients' scores over time via a clinician dashboard (eFigure 2). The dashboard displayed all the patients in the clinic who were in the intervention group and showed their model scores over time. The dashboard could be sorted by patient name and model value.

Description of user experience and acceptability survey

A product experience survey created by the company and approved by the Partners IRB was administered either in person or over the telephone by the BWH Research Associate after the exit survey at the end of the study to patients in the intervention group. Product experience data was collected from 15 patients (55.6%) in the intervention group. The survey assessed technical difficulties with the application, "Did you have any technical difficulties with the app?" (yes/no) and if yes, what were these difficulties and were they resolved. Three patients (20%) reported a technical issue. One person reported difficulties with setting up the app, one reported they got a new phone and

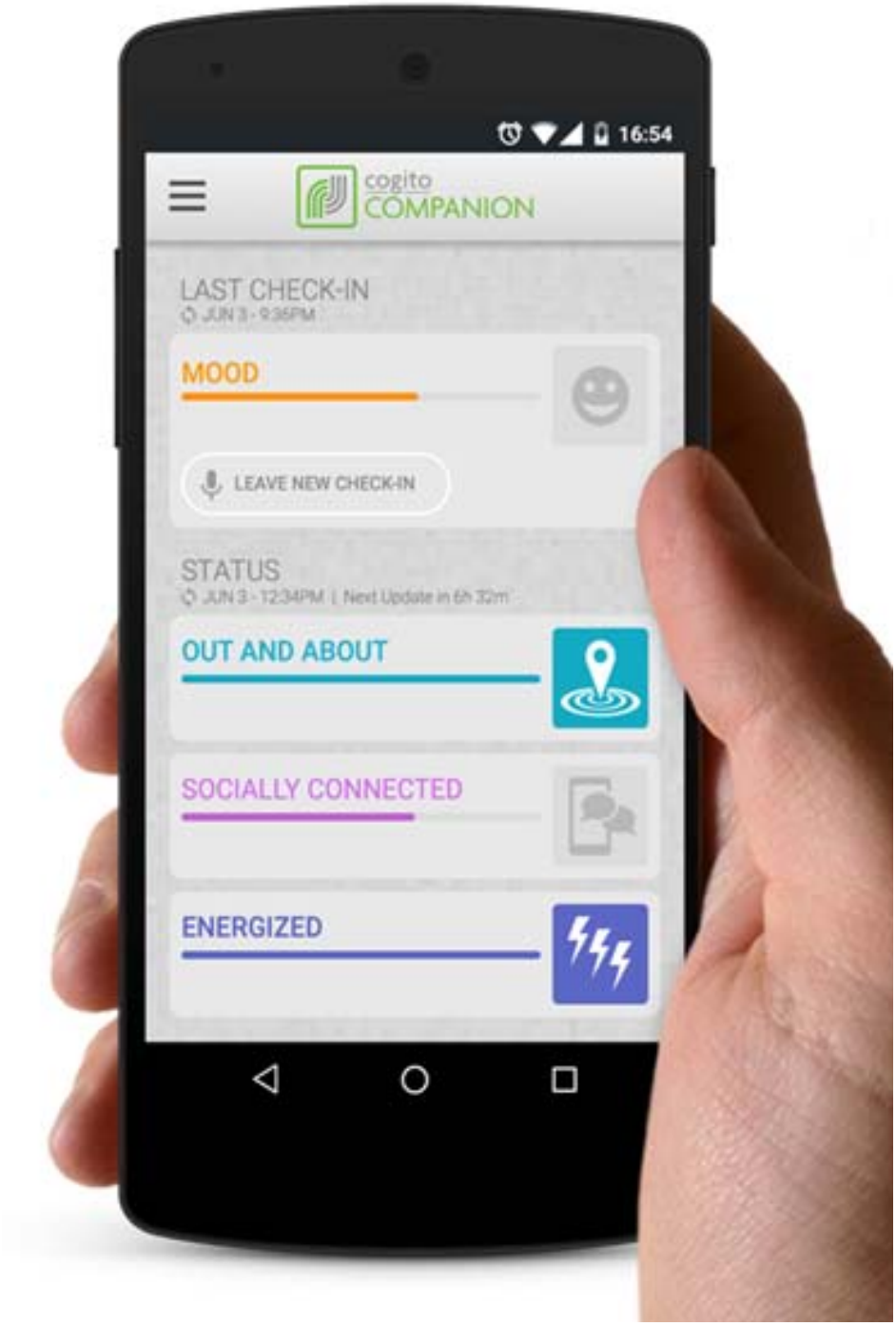
could not log into the application, and one person reported that the application was no longer working. All were satisfied with the resolution of these issues after contacting study staff. Self-reported phone behavior changes were assessed by asking, “Did you call, text, or use your phone less often than usual during the duration of the study?” (yes/no). Thirteen of the 15 patients (86.7%) reported they did not use their phones differently during the study period. None of the patients reported uninstalling the application from their phones before the study period ended.

Questions also asked about acceptability and effect of the mobile monitoring system. Patients answered how likely they would be to share scores with behavioral health care providers, primary care physicians, other healthcare providers, friends, family and on social media (5-point scale from 1= not at all likely to 5=definitely). Patients also reported whether using the application improved their communication with their healthcare providers, made them feel more engaged in their own health, and improved their self-care compared with not using the app (10-point scale from 1=no change, 5=somewhat, to 10=very much so). Patients also reported whether they directly discussed the mobile monitoring scores with their provider (yes/no). Patients were also asked compared to other applications whether they believed this mobile monitoring system respected their privacy (10-point scale from 1=no change, 5=somewhat, to 10=very much so).

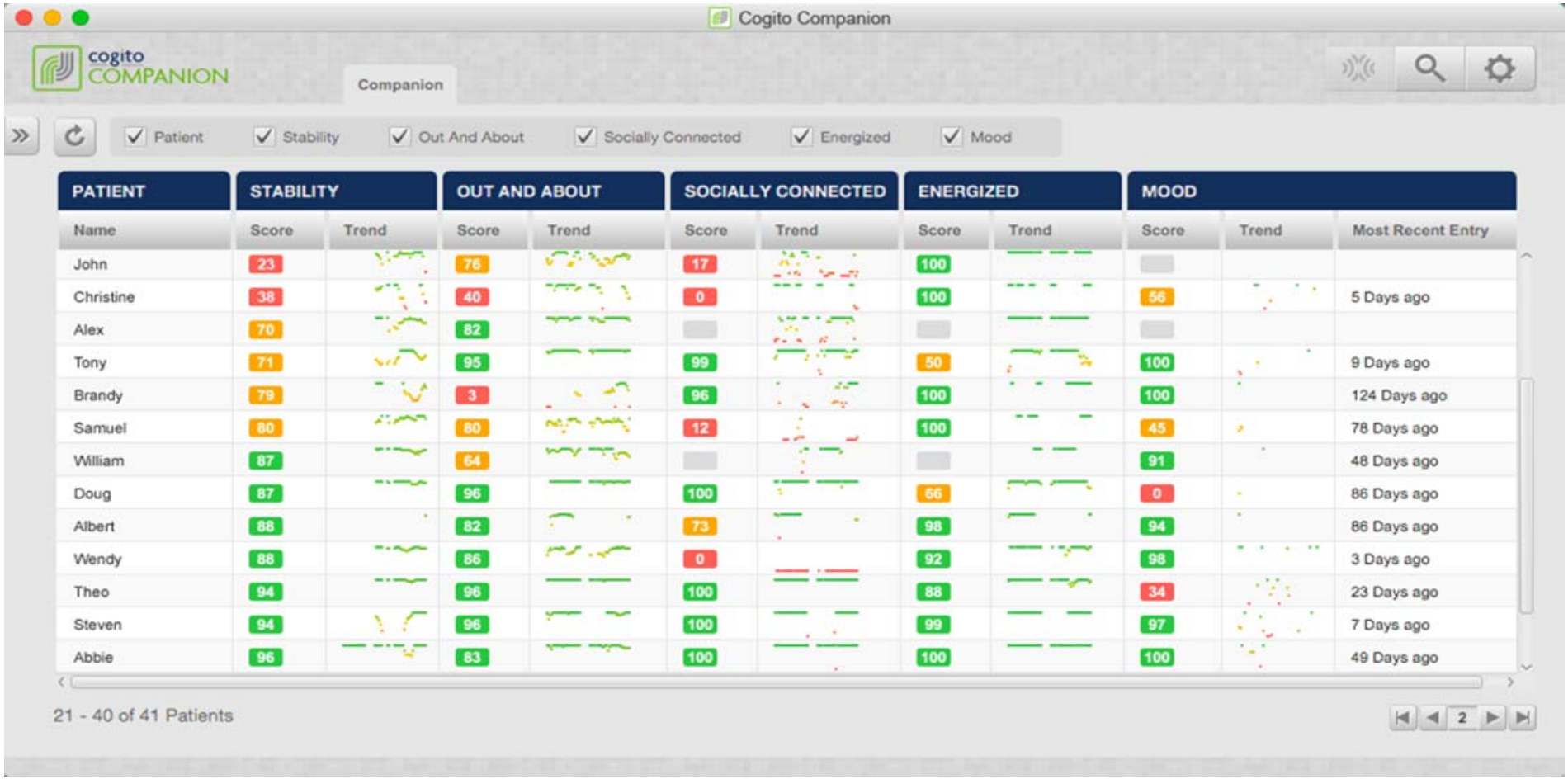
Description of analysis

We used two mixed-design one-within, one-between Analyses of Variance with repeated measures on the assessment time factor for our two primary outcomes: the Patient Health Questionnaire (PHQ-9) and Schwartz Outcome Scale (SOS-10). Significance level was set at $p<.05$. Data was analyzed beginning in July 2018. Final data analysis was conducted in November 2019.

eFigure 1. Patient View of Mobile Monitoring System Smartphone Application



eFigure 2. Clinician View of Desktop Dashboard



eReferences.

1. Place S, Blanch-Hartigan D, Rubin C, et al. Behavioral Indicators on a Mobile Sensing Platform Predict Clinically Validated Psychiatric Symptoms of Mood and Anxiety Disorders. *Journal of Medical Internet Research*. 2017;19(3):e75