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On Site: Can Trials Be Conducted 100% via Mobile App? Results Say Yes

The BRIGHTEN clinical trial recently brought mental health into the 21st century using mobile technology to conduct a trial from patient recruitment to final assessment, including the delivery of the treatment interventions. The trial was led by Dr. Patricia Areán, a licensed clinical psychologist and professor of Psychology and Behavioral Sciences at the University of Washington.

BRIGHTEN (Bridging Research Innovations for Global Health through Technology, Emotion and Neuroscience) is a mobile research platform. The platform enables data to be collected on mood, cognition, physical and social activity via smart phone apps and social media. Using BRIGHTEN, the research team compared three types of mood apps to treat depression in adults. One of the most notable aspects of the trial was the number of participants: more than 2,900.

When asked if she was surprised by the number of participants recruited for BRIGHTEN, Dr. Areán said, "Very! We originally planned to recruit 150 people, and we met that in one week. We asked NIH and our IRB to keep going with recruitment and we were blown away."

Drew Schiller is chief technology officer and co-founder of Validic, a digital health platform that takes patient-generated data from apps, wearables and in-home medical devices and connects it to the healthcare system. He said, "Recruiting 150 participants for any trial is a challenge — the fact that this was done in one week shows the power of technology. Digital health is streamlining recruitment processes and allowing for better participant engagement and health insights during trials."

The group of participants was ethnically similar to the 2013 U.S. Census and included residents from eight of the 15 most rural states in the U.S. More than half the participants were aged 18 to 30, although 5% of participants were aged 61 to 76.

In addition, the study cost $500,000, which is significantly less than that of a typical clinical trial.

Said Schiller, "Clearly, this is a model for trials of the future, and digital health will continue to play an important role in reducing costs and improving access to trial participants."

Dr. Areán believes all-tech trials are suitable for any randomized trial, survey or longitudinal study. "Concerning health indications, pretty much any study looking at lifestyle, behavior or mental health would apply," she said.

Christopher Benko, CEO of Koneksa Health, a company whose software remotely captures and converts real-world data from patients, said, "The idea of an all-tech trial is intriguing and the BRIGHTEN study demonstrates important examples of what can be accomplished with technology. However, in the U.S., where 85% of clinical outcome assessments are still collected on paper, I think there is a lot of low-hanging fruit. I don't see a reason to focus on 'all-tech' just for tech's sake."

The industry agrees that mobile apps ultimately have many uses. Benko said, "Mobile apps might be appropriate for behavioral interventions, but technology also has the potential to complement drug or device studies by enabling continuous monitoring of patients through biosensors, eCOAs or telemedicine assessments by a clinician."

The main challenge of the study was a common concern for remote research: keeping participants engaged. During the 12 weeks the trial was conducted, 66% of participants lasted four weeks, 50% made it to eight weeks, and 41% completed the full 12-week study.

In assessing the retention challenge seen in the BRIGHTEN trial, the research team observed that rates were still higher than the average Internet-based, randomized, controlled trial, but also noted that the trial was completely automated, with very little interaction between the participants and the research team. Research has shown that a hybrid approach can boost retention, incorporating more direct contact via video streaming and other technology.

The research team experimented with two different incentive methods to improve retention. They found that participant payment was not sufficient, and that, while bonus pay motivated participants to complete their assessments, it stopped short of prompting them to actually use the trial's apps. These results echo the findings of previous studies, which have shown that externalized rewards like payment can decrease motivation, and adherence improves in response to internalized rewards, like an individualized presentation of study progress and personalized encouragement.

While the research team is still analyzing the data collected, early analysis shows that all three depression apps tested positively affected mood and disability over time.

The larger significance of the BRIGHTEN study is that it showed how mobile technology can be successfully harnessed to recruit patients, obtain ethnically diverse participants from remote areas, and treat depression as well.

Already looking to the future, Dr. Areán said, "Now, we are going to repeat this study in Spanish. We have also applied for funding to look at gene, lifestyle and environment interactions and the impact they have on disease."

— Lisa Chontos

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