Title: Effect of the Apple Watch ECG and Irregular Rhythm Notification Detection Features on Patient-Reported Outcomes and Clinical Utilization: A Randomized, Controlled Trial

Technology of Interest: Apple Watch Diagnostic + mHealth

Disease Area: Cardiovascular Medicine
Duration: 12 months

Network Collaborator(s): Yale New Haven Hospital; Duke University Health System; Mayo Clinic

The objective of this Test-Case is to assess the effect of the Apple Watch’s ECG and irregular rhythm notification detection software features on both patient-reported outcomes and clinical utilization. The pace of innovation for digital health technologies is accelerating. However, several potential risks are inherent to these new technologies, including misinterpretation and/or overreliance on the device-generated data, as well as false negatives and false positives. Therefore, the clinical impact of these devices must be assessed through active surveillance to guide future labeling and risk mitigation strategies.

Using Hugo, a participant-centered mobile health research platform for data collection and aggregation, this study will gather and collate patient-reported outcomes, healthcare utilization data, and data from personal digital devices. 150 patients with atrial fibrillation who undergo planned outpatient cardioversion will be randomly allocated to receive the Apple Watch or usual care and will be followed for six months. The primary study endpoint is the validated Atrial Fibrillation Effect on Quality-of-life (AFEQT) questionnaire global score at 6 months compared to baseline. Secondary endpoints include additional clinical treatment for atrial fibrillation and differences in clinical utilization between participants who receive the Apple Watch and the control group. Finally, we will assess the Apple Watch’s ability to serve as a tool for post-market ECG surveillance monitoring by examining its accuracy compared to 12-lead ECGs obtained in routine clinical care.
Leveraging patient-generated health data, this project will assess the impact of a mobile-delivered, prescription digital therapeutic (PDT)* device (Pear-003) delivering Cognitive Behavioral Therapy for Insomnia (CBT-I) for real-world patients with chronic insomnia and depression.

Insomnia is one of the most prevalent health concerns and imposes a significant physical, behavioral, and financial burden on patients' lives. Up to 50% of the general adult population experience insomnia symptoms, with 12-20% meeting criteria for chronic insomnia. Adults suffering from insomnia also have a higher likelihood of comorbid conditions such as depression, resulting in a reduced quality-of-life and higher rates of morbidity and mortality. CBT for insomnia is the recommended first line treatment for chronic insomnia, but many patients encounter treatment barriers, including a limited number of trained providers. The goal of this Test-Case is to conduct a multi-center randomized controlled trial to collect and evaluate real-world data alongside clinically-validated measures of insomnia and depression to yield a multidimensional analysis of patient benefit from a mobile-delivered CBT-I prescription digital therapeutic.

Using Hugo, a participant-centered mobile health research platform for data collection and aggregation, this study will gather and collate patient-reported outcomes, healthcare utilization data, and data from personal digital devices. 70 patients with chronic insomnia and sub-clinical depression will be randomly allocated to receive the PDT device delivering CBT-I or usual care and will be followed for 21 weeks. Primary study endpoints include self-reported online ratings of insomnia severity and self-reported depressive symptoms. Secondary endpoints include rate of healthcare utilization, change in sleep outcomes, and change in patient-reported outcomes of sleep quality. In addition, this study will determine the feasibility of connecting in-house PDT devices to other mobile health (mHealth) devices.

*Planned; this product has not yet been reviewed and approved by the FDA.