

Omada Health to launch largest clinical trial of digital DPP

By [Dave Muoio](#)

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Omada Health has made plans with the University of Nebraska Medical Center (UNMC) and Wake Forest University to conduct the largest randomized controlled study of a digital diabetes prevention tool yet, according to the digital therapeutic company.

“What’s really exciting about this clinical trial is that we also are studying how best to integrate effective, scalable preventive services, especially digitally-enabled ones, into typical clinical practice,” Paul A. Estabrooks, distinguished chair in the Social and Behavioral Health Department at UNMC and principal investigator of the study, said in a statement. “In fact, we’ll be able to shed some light on strategies that will really speed the translation of high-quality, research-tested diabetes prevention interventions into sustained clinical practice.”

The Preventing Diabetes With Digital Health and Coaching (PREDICTS) study is estimated to enroll 484 adults and conclude in September 2019, according to the study’s [clinicaltrials.gov](#) page. Participants with HbA1c levels within pre-diabetic ranges will be randomly assigned to receive either UNMC’s standard care or intervention using Omada’s digital diabetes prevention program.

The study’s primary outcome measure will be the percent reduction of HbA1c over the course of 12 months, with secondary measures including weight loss and changes in cardiovascular risk. However, the study will also monitor uptake characteristics that have previously received less attention in such studies, including quality of life, healthcare utilization, and study staff’s perceptions of implementation.

“Our goal at Omada has been to continually set new standards for what the industry should expect when it comes to the effectiveness of digital healthcare interventions,” Omada cofounder and CEO Sean Duffy said in a statement. “The PREDICTS trial is the next step in that evolution — it will track a range of healthcare and other outcomes, while establishing



the highest level of clinical evidence for the effectiveness of a digitally-delivered intensive behavioral counseling program.”

Study participants will be recruited at UNMC, which will also be responsible for data collection and implementation analysis. Wake Forest researchers will head data system management and quality operational reports, while Omada will take charge of the study’s experimental arm and outcome data.

“Even with the research to date in published literature, there is still some debate about the efficacy of virtual programs; the outcomes of the PREDICTS trial should help resolve these concerns and move policy towards accepting digital [diabetes prevention program] as a proven, evidence-based and effective means to reduce risk for costly chronic diseases,” Cynthia Castro Sweet, clinical research director at Omada, said in a statement.