



## WellDoc publishes mobile diabetes study

By Brian Dolan  
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WellDoc released this week the pre-print version of the first randomized controlled trial (RCT) study using a mHealth solution (WellDoc's DiabetesManager) to track reduction in blood glucose levels over one year compared against usual methods. According to the study results, "the mean decline in A1C (the gold-standard measure for diabetes control) was 1.9% in the intervention group and 0.7% in the usual care group, a difference of 1.2%."

The Mobile Diabetes Intervention Study (MDIS), conducted by the University of Maryland School of Medicine, is scheduled to be published in the September issue of the American Diabetes Association's (ADA) publication Diabetes Care.

"We studied the impact of combining web and mobile based patient coaching with clinical decision support for community primary care providers, and compared this approach with standard diabetes management or usual care alone." stated Charlene C. Quinn, RN, PhD, University of Maryland School of Medicine and lead investigator of the study, in a press release. "The trial results indicate that doctors and patients can engage more effectively using mobile health tools like the WellDoc system to enhance patients' diabetes care and their blood glucose." According to the study, a clinically significant change in A1C occurred whether patients began the trial with a high or low A1C.



WellDoc is set to release the WellDoc DiabetesManager commercially this fall, which received FDA clearance one year ago. They announced integration with Allscripts EHR last December and a partnership with AT&T last fall. Back in 2009, WellDoc published the results of a three month study using their Virtual Coach monitoring software that had a 2% reduction in A1C compared to a control group.

WellDoc, a healthcare company that develops technology solutions aimed at engaging patients in positive behavior change, optimizing clinical decisions, and improving health outcomes, today announced the pre-print version of a study scheduled to be published in the September issue of Diabetes Care, the world's preeminent diabetes focused scientific journal, published by the American Diabetes Association (ADA). The randomized controlled trial (RCT), using a mobile health (mHealth) solution manufactured by WellDoc, met the primary endpoint of reduction in blood glucose levels over one year vs. treatment via usual care alone (control).

Conducted by the University of Maryland School of Medicine, the Mobile Diabetes Intervention Study (MDIS) (n=163) is the first RCT of a mobile phone-based diabetes coaching and decision support intervention conducted over a one-year treatment period. The mean decline in A1C (the gold-standard measure for diabetes control) was 1.9% in the intervention group and 0.7% in the usual care group, a difference of 1.2% ( $P < .001$ ). A clinically significant change in A1C was seen whether patients began the trial with a high or low A1C (e.g., above or below baseline of 9%).

Today there are approximately 26 million people in the United States living with diabetes. 63% of people with type 2 diabetes have A1C levels above the ADA recommended level of less than 7%[1]. This pandemic costs our nation \$174 billion per year according to the Centers for Disease Control (2010). Yet, it is estimated that every one percentage point drop in A1C can reduce by 37% the risk and costs of complications such as eye, kidney, and nerve disease[2].

“We studied the impact of combining web and mobile based patient coaching with clinical decision support for community primary care providers, and compared this approach with standard diabetes management or usual care alone.” said Charlene C. Quinn, RN, PhD, University of Maryland School of Medicine, lead investigator of the study. “The trial results indicate that doctors and patients can engage more effectively using mobile health tools like the WellDoc system to enhance patients’ diabetes care and their blood glucose.”

“Patient-centered team care is vital to achieving successful glycemic control but difficult to implement.” said Richard Bergenstal, M.D., Executive Director of the International Diabetes Center at Park Nicollet and past president of the American Diabetes Association (ADA). “Finally we have a good example of utilizing technology in the form of mobile diabetes coaching to help both patient and provider make the most effective lifestyle and management decisions and facilitate the essential team support and communication that yields the desired improvement in glucose control.”

“Improved care coordination is a significant factor in gaining better patient outcomes, particularly for patients with chronic conditions such as type 2 diabetes,” said Jon P. Shematek, M.D., Senior Vice President and Chief Medical Officer for CareFirst® BlueCross BlueShield. “Ultimately, by making lasting improvements in care coordination and quality we can better control costs for the health industry as a whole.”

This fall, WellDoc is commercializing the WellDoc DiabetesManager®, the first mHealth solution cleared by the FDA to provide automated, real-time behavioral patient coaching and clinical decision support for their doctors. Powered by the WellDoc Automated Expert Analytics System™, the software-based system redefines existing conventions of diabetes management for people with type 2 diabetes, providing support to their healthcare providers to extend their care beyond traditional office visits. The WellDoc DiabetesManager is indicated for use by healthcare providers and their adult patients with type 2 diabetes, and is not intended to replace the care provided by a licensed healthcare professional, including prescriptions, diagnosis, or treatment.

“That this study met the primary endpoint of change in A1C over one year treatment period, for me, personally validates my departure from clinical practice six years ago to pursue an idea that could make a real difference in the lives of people with diabetes and their doctors.” said Suzanne Sysko Clough, MD, founder & chief medical officer, WellDoc. “We hope to see more mHealth trials that reveal the benefits of clinically relevant, non-pharmacologic products designed to support the daily management of various chronic diseases.”

Dr. Quinn presented the results of the trial in June during a clinical symposium at the ADA 71st Scientific Sessions and they will be presented again at the annual American Diabetes Educators Association (AADE) meeting in Las Vegas on August 3rd at 4pm PDT. The study is available at <http://care.diabetesjournals.org/>