

Cognitive behavioral therapy via smartphone lowers blood sugar, improves health behaviors in patients with diabetes

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People with Type 2 diabetes who were given a smartphone app that delivers personalized cognitive behavioral therapy (CBT) saw



significantly greater reductions in their blood sugar and less need for higher doses of diabetes medications at six months compared with those who only received standard diabetes care and a control app, in a study presented at the American College of Cardiology's Annual Scientific Session Together With the World Congress of Cardiology. A clear "dose effect" was seen, with patients completing more CBT lessons seeing the greatest benefits.

"When studied in a large randomized controlled trial, digital CBT tailored to the individual reduced <u>blood sugar</u> levels, while also reducing the need for intensified medication use and improving <u>blood pressure</u> and body weight," said Marc P. Bonaca, MD, MPH, professor of medicine and director of vascular research at the University of Colorado School of Medicine in Aurora, Colorado, and the study's principal investigator. Digital CBT also had a positive effect on patient-reported outcomes, including depression and quality of life scores over six months, he said.

This is one of the first digital therapeutics to demonstrate efficacy for lowering blood sugar in a rigorous randomized controlled trial and has the potential to become one of the first prescription digital therapeutics for diabetes, Bonaca said.

Lifestyle modification is the foundation of diabetes management to reduce <u>blood sugar levels</u> and the long-term consequences of elevated blood sugar, which can include high blood pressure, heart disease and stroke, he said. Health care professionals, however, have struggled to help patients achieve effective lifestyle change, Bonaca said.

For example, traditional one-on-one CBT delivered in a therapist's office has been shown to be effective, but it is expensive and may not be covered by health insurance. Access to CBT is also limited by the availability of therapists and the need to travel to the therapist's office.



"Much of diabetes stems from unhealthy behaviors—making poor food choices, overeating, stress eating, not exercising—that are generally rooted in unhelpful patterns of thinking and modes of coping with environmental stresses," Bonaca said. "CBT has been shown to be effective at helping people develop the skills to recognize the unhelpful thoughts and beliefs that trigger their unhealthy behaviors and to establish healthier patterns of thinking and behavior."

The trial enrolled 668 people with diabetes whose average age was 58 years and average body mass index (BMI) was 35. A BMI of 30 or higher falls within the obesity range. Fifty-six percent of those enrolled were women, 30% were Black and 15% were Latino. At study enrollment, participants were taking an average of two medications to control their blood sugar levels.

Their median level of hemoglobin A1c (HbA1c), a measure of average blood sugar levels over the past two to three months, was 8.1%. The threshold for a diagnosis of diabetes is over 6.5%. Participants were required to have a smartphone.

"For this trial, we wanted to know if a CBT program for diabetes that was automated and personalized would be effective," Bonaca said. "We wanted something that users could access on a smartphone that would deliver benefit through lessons and skills and that would be individually tailored through a process of asking questions."

Half of the participants were randomly assigned to the CBT app (BT-001) and half to a control app, which asked some questions but did not provide tailored lessons or skills. Those assigned to the CBT app were asked to complete one lesson per week aimed at skill development and behavior change but could complete more lessons if they wished.

The primary endpoint was the change in HbA1c levels at three and six



months. Secondary endpoints included changes on standardized scales measuring patient-reported outcomes such as depression and quality of life. Changes in the use of medication to control blood sugar levels was a prespecified exploratory endpoint (an endpoint included to explore a new hypothesis).

At three months, participants assigned to the app saw a reduction in HbA1c of 0.4%, which was statistically significant and similar in magnitude to what is achieved with most antihyperglycemic medications. At six months, these participants maintained this reduction, which remained statistically significantly lower than the control group.

At the end of the study, 24% of patients in the control group had an increase in <u>medical therapy</u> compared with 14.4% in the BT-001 arm. In addition, while more participants in the <u>control group</u> started insulin or increased their dose, more participants in the BT-001 group discontinued insulin or were able to lower their dose.

"We saw a clear dose effect with digital CBT," Bonaca said. "That is, the antihyperglycemic effect increased in direct proportion to the number of lessons participants completed. The more lessons they did, the greater the reductions in HbA1c they achieved. Participants aged over 75 did as well as younger patients if they completed the same number of lessons."

The CBT program was not time consuming, he said, with users typically spending less than six minutes a day using the app.

Bonaca and his colleagues as well as other groups are conducting followup studies to learn more about the impacts of digital <u>cognitive behavioral</u> <u>therapy</u> in different delivery models and for longer exposures.

In addition to holding his position at the University of Colorado School of Medicine, Bonaca is executive director of CPC Clinical Research, a



nonprofit academic research organization affiliated with the University of Colorado.

More information: Conference: accscientificsession.acc.org/

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