**Title: AHA 22: BT001 PIVOTAL: Nutritional Cognitive Behavioural Therapy in Patients with Type II Diabetes**

**Participants: Dr Marc Bonaca**

**Date: 04/11/2022**

**Dr Marc Bonaca**

"- My name is Marc Bonaca. I'm a cardiologist and a vascular medicine specialist at the University of Colorado in the United States. I'm a professor of medicine, director of vascular research and the executive director of CPC. And I'll be talking about a new digital nutritional cognitive behavioural therapy for patients with type 2 diabetes.

**Device Studied**

This is a digital therapeutic, it's an app. It's made by a company called Better Therapeutics named BT-001 and it's an app for patients with diabetes but it's very different than many that are out there that have you track your calories or just follow your blood sugar, other things. Really what this app does is it delivers something called cognitive behavioural therapy or nutritional cognitive behavioural therapy. Now, cognitive behavioural therapy is actually something that's been around for a long time and that really targets are behavioural or things such as substance addictions, pain, other things like that where patients have core thoughts and beliefs that are sort of misguided, if you will. And those lead to unhelpful behaviours. And those unhelpful behaviours manifest in things like food choices, what you eat, when you eat, exercise, and that perpetuates the cycle, the progressive cycle of type 2 diabetes. And what this app delivers is a personalised structured cognitive behavioural therapy that helps patients to help themselves by resetting those core thoughts and beliefs that then translate to helpful behaviours around food, eating and exercise, and actually can help to lead over reverse type 2 diabetes. And that was the study that we did.

**Patient Population and Study Design**

So this was a randomised controlled clinical trial, so that it was not just a single arm but it was a very rigorous registration type trial randomised to BT-001 or a control app. There were 12 sites in the United States that recruited almost 700 patients. Eligible patients were those with type 2 diabetes that were not on prandial insulin or weren't unstable but otherwise it was quite liberal in terms of who was included. Generally, people with an A1C that were 7% or above and that were on stable antihyperglycemic therapy.

**Key Findings**

Well, we learned in terms of key findings that use of BT-001 relative to control as a randomised trial led to a statistically significant reduction in Haemoglobin A1C with a delta between the control group and the BT group of about 0.4% over the first 90 days. And then in this current analysis, we learned that that delta, that benefit was persistent through actually 180 days. And that the BT group continued to have a reduction in Haemoglobin A1C and the delta between control and BT-001 remains statistically significant. And so we learned that there was a persistent reduction in Haemoglobin A1C, but that's not the whole story, because the other key finding is that because physicians in this study were able to see the Haemoglobin A1C and change medications obviously in the control group, there was more medication intensification. And so we saw that there was a 7% absolute reduction in the need for new or intensified antihyperglycemic medications with BT-001. That was statistically significant, highly significant p-value. So lower A1C, fewer new medications or intensification of medications, and then along with that were statistically significant and important changes in body weight about a four pound difference in weight between BT-001 and control, and a statistically significant reduction in blood pressure. And so all of those findings were consistent. And actually, we asked patients how they felt using structured patient reported outcome measures, there were improvements in their physical component scores as well as depression screening.

**Impact on Daily Practice**

Yeah, we hope that these findings have a profound impact in clinician daily practice. There are a lot of new and important medications out there for diabetes and of course that's an important development. But the foundation of treatment for type 2 diabetes is lifestyle modification. Yet for all clinicians and I speak as a clinician myself with many patients with diabetes having patients change behaviour based on interactions in the clinic that last a few minutes, it's very difficult and not successful in the majority of patients. And other more intensive measures like traditional cognitive behavioural therapy, it's just not feasible. It costs a lot of money. It requires people coming to the hospital or the clinics, spending multiple sessions per week. And so it's just not scalable. And this then becomes a tool that a clinician could simply prescribe. And that would enable a patient to access nutritional cognitive behavioural therapy in their own home on their own schedule in a very personalised and private way. And really promises to move the foundation of behavioural change to the forefront and make it feasible and scalable for clinicians and patients alike. And so we hope this becomes a transformative technology.

**Take-home Messages**

My take-home message for this would be that we can broadly achieve behavioural change in type 2 diabetes as a way of reversing the core problem. And we can do it by leveraging technology and establish mechanisms of action such as nutritional cognitive behavioural therapy. And now we have proof that that approach works. And the next question will be how we integrate it into our clinical practice.

**Future Directions**

Two things in terms of future directions. First, unlike many of the therapies that we think about for cardio metabolic disease here we saw lower rates of adverse events with the intervention than control. And that was quite a striking finding. And it begs the bigger question of, okay, you can lower A1C, lower body weight, all of those things, what does that translate into long-term in terms of healthcare utilisation and outcomes? And ongoing now are several real world evidence studies using this exact technology to describe the healthcare utilisation in real world patients. And so the next step I think will be to understand the broader implications of BT-001 as a foundational therapy in patients with type 2 diabetes.”