

News Release

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New Study Shows Open-Source Automated Insulin Delivery is a Safe and Effective Treatment Option for People with Type 1 Diabetes

First-of-Its-Kind Study Compares Open-Source Automated Insulin Delivery to Sensor-Augmented Pump Therapy

NEW ORLEANS, La. (June 6, 2022) – Results from the CREATE Trial demonstrated open-source automated insulin delivery (AID) systems are a safe and effective therapy for people with type 1 diabetes. Findings from the randomized controlled trial (RCT) comparing open-source AID to sensor-augmented pump therapy (SAPT) were presented today at the 82nd Scientific Sessions of the American Diabetes Association® (ADA).

Open-source AID systems were developed to reduce the burden of living with diabetes by combining an insulin pump, continuous glucose monitor (CGM), and an algorithm that automatically adjusts insulin delivery every five minutes to keep glucose levels in target range. The technology was developed by people with diabetes and shared openly, commonly referred to as open-source, so that others could evaluate the system and choose to use it themselves. These open-source systems were available for years before commercial AID systems and are used by people with type 1 diabetes worldwide.

The CREATE Trial is the first randomized controlled trial to evaluate the safety and efficacy of the most commonly used open-source AID system. The study compared open-source AID, using the OpenAPS algorithm from a version of AndroidAPS implemented in a smartphone with the DANA-i™ insulin pump and Dexcom G6® CGM, to SAPT. A diverse population of patients, many of whom had little or no experience with AID, were recruited to a 24-week, multi-center RCT, which included children (7–15 years) and adults (16–70 years), to examine efficacy and safety of open-source AID.

Results of the trial included:

- The primary outcome was the percent of time in target sensor glucose range (TIR; 3.9-10 mmol/L [70-180 mg/dL]) between open-source AID and SAPT during the last two weeks of the RCT.
- Both children and adults achieved more time in range (TIR), when using the open-source AID system compared to treatment without automation (SAPT).

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- 97 patients (48 children and 49 adults) were randomized.
- The overall treatment effect resulted in a 14% difference in TIR, favoring the open-source AID treatment group.
- Mean TIR (\pm SD) at study end was 74.5 \pm 11.9% using AID (Δ + 9.6 \pm 11.8% from run-in; P<0.001) for adults and 67.5 \pm 11.5% (Δ + 9.9 \pm 14.9% from run-in; P<0.001) for children. TIR did not improve in the SAPT group.
- 60% of participants using open-source AID met the TIR target set by international guidelines of >70%, compared to just 15% in the SAPT arm.
- Only two participants withdrew from AID due to hardware issues.
- No severe hypoglycemic or diabetic ketoacidosis events occurred in either treatment group. There was no increase in overall hypoglycemia.
- The improvement in time in range in both children and adults using open-source AID was immediate and sustained for the study duration.

“We were encouraged to see the greatest improvements in time in range were in those who had the lowest time in range at the start of the study. This supports the finding that a wide range of people with diabetes who want to use this technology could benefit from it, regardless of their outcomes with previous therapies,” said Dana Lewis, diabetes researcher, a founder of the open-source artificial pancreas movement, OpenAPS, and study investigator.

“While open source AID is not yet approved by the FDA, we know people worldwide are using it to manage their diabetes. Our findings demonstrate that this is a safe and effective technology and adds to the body of evidence supporting use of open-source AID for improving glycemic outcomes,” commented Dr. Martin de Bock, pediatric endocrinologist at the University of Otago, Christchurch, New Zealand, and lead investigator of the study.

The authors hope these findings provide both people with diabetes and clinicians with additional information to use when evaluating open-source AID options for people living with diabetes.

Research presentation details:

Dr. de Bock, in conjunction with study investigators, presented the findings of the trial during the oral presentation listed below:

- [The CREATE Trial: Randomized Clinical Trial Comparing Open-Source Automated Insulin Delivery with Sensor Augmented Pump Therapy in Type 1 Diabetes](#)
- Presented on Monday, June 6 from 2:15–2:30 p.m. CT

For more information, please contact the ADA Scientific Sessions media team onsite at the Ernest N. Morial Convention Center from June 3–7 by phone at 504-670-4902, or by email at SciSessionsPress@diabetes.org.



82ND SCIENTIFIC SESSIONS
HYBRID | NEW ORLEANS | JUNE 3-7, 2022

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About the ADA's Scientific Sessions

The ADA's 82nd Scientific Sessions, the world's largest scientific meeting focused on diabetes research, prevention, and care, will be a hybrid event held June 3–7, 2022 at the Ernest N. Morial Convention Center in New Orleans, LA. Leading physicians, scientists, and health care professionals from around the world will unveil cutting-edge research, treatment recommendations, and advances toward a cure for diabetes. We are eager to get back to safely participating in person and networking with colleagues while hearing the latest scientific advances and groundbreaking research presentations. Learn more and register at scientificsessions.diabetes.org and join the Scientific Sessions conversation on social media using #ADA2022.

About the American Diabetes Association

The American Diabetes Association (ADA) is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For 81 years, the ADA has driven discovery and research to treat, manage, and prevent diabetes while working relentlessly for a cure. Through advocacy, program development, and education we aim to improve the quality of life for the over 133 million Americans living with diabetes or prediabetes. Diabetes has brought us together. What we do next will make us Connected for Life. To learn more or to get involved, visit us at diabetes.org or call 1-800-DIABETES (1-800-342-2383). Join the fight with us on Facebook ([American Diabetes Association](https://www.facebook.com/AmericanDiabetesAssociation)), Spanish Facebook ([Asociación Americana de la Diabetes](https://www.facebook.com/AsociaciónAmericanaDeLaDiabetes)), LinkedIn ([American Diabetes Association](https://www.linkedin.com/company/american-diabetes-association)), Twitter ([@AmDiabetesAssn](https://twitter.com/AmDiabetesAssn)), and Instagram ([@AmDiabetesAssn](https://www.instagram.com/AmDiabetesAssn)).

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