

Eighteen-month follow-up comparison of simplified meal announcement vs. precise carbohydrate counting in adolescents with type 1 diabetes using the MiniMed™ 780G Advanced Hybrid Closed-Loop System¹

Objective

To compare the glycemic control in adolescents (age 12-18 years) with Type 1 diabetes (T1D) on MiniMed™ 780G system with simplified meal announcement (Fix) vs. precise carbohydrate counting (Flex) over an extended period of 18 months.



Exact carb counting is not required to succeed with the MiniMed™ 780G system

International targets of glycemic control met for both groups over an extended period of time.



MiniMed™ 780G system increased Time in Range in both Fix & Flex groups

Fix TIR increase: 25.7% | Flex TIR increase: 31.8%.



Reduction in Time Above Range with MiniMed™ 780G

Fix TAR decrease: 21.7% | Flex TAR decrease: 17.2%.



No significant difference in A1C

between the Fix (6.9±0.6%) and Flex groups (6.6±0.7%) at 18 months (p=0.162).

Outcomes

Using the MiniMed™ 780G system with a simplified meal announcement, adolescents can achieve and maintain the international targets of glycemic control over an extended period (18 months); however, carbohydrate counting resulted in superior TIR.

Due to inherent analysis limitations, caution is advised when attempting to extrapolate these results to new patients (and different populations and ages). There could be significant differences. Study weaknesses include a relatively small sample size and exclusion criteria for those with limited carb counting skills.

1. Petrovski G, et al. Diabetes 2024;73(Supplement_1):1905-LB. doi.org/10.2337/db24-1905-LB
 2. Petrovski G et al. Diabetes Care 2023; 46(3):544-550. doi:10.2337/dc22-1692.
 3. Petrovski G et al. Diabetes technology & therapeutics. 2024; 26(S3):76-83. doi:10.1089/dia.2023.0429.

Design

- Adolescents with T1D were randomly distributed in a 1:1 ratio to utilize the MiniMed™ 780G system in conjunction with either the “flex” or “fix” meal announcement methods.¹
- Participants were followed for 18 months with data analysis at 3, 6, 12 and 18 months.
- The primary endpoint was the difference in time-in-range (TIR), and secondary endpoints included glycated hemoglobin (HbA1c) and other glucose and insulin metrics.

Outcome parameters

At 18 months, TIR (70-180 mg/dL) was significantly higher in the flex versus fix group (80.9% versus 73.2%, respectively; p=0.001). There was no significant difference in HbA1c between the fix (6.9±0.6%) and flex groups (6.6±0.7%) at 18 months (p=0.162). Glucose target of 100mg/dL, active insulin time of 2 hours and rule of 360 for carb ratio were used in >90% of participants in both groups.

MiniMed™ 780G insulin pump system

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Simplified meal announcement study



12 month follow-up study



18 month follow-up study

Important Safety Information for MiniMed™ 780G system with SmartGuard™ technology with Instinct sensor, Simplera Sync™ sensor, and Guardian™ 4 sensor: The MiniMed™ 780G system is intended for the continuous delivery of basal insulin at selectable rates and the administration of insulin boluses at selectable rates for the management of type 1 diabetes mellitus in persons 7 years of age and older, and of type 2 diabetes mellitus in persons 18 years of age and older requiring insulin. The system is also intended to continuously monitor glucose values in the fluid under the skin. The MiniMed™ 780G System includes SmartGuard™ technology, which can be programmed to automatically adjust insulin delivery based on the continuous glucose monitoring (CGM) sensor glucose values and can suspend delivery of insulin when the sensor glucose (SG) value falls below or is predicted to fall below predefined threshold values. The system is intended for use with connected sensors, including the Simplera Sync™ and Guardian™ 4 sensors and integrated continuous glucose monitors, including the Instinct sensor, each of which has different wear-time, form factor, insertion site, and other distinguishing characteristics that relate to sensor performance. Consult the appropriate sensor user guide when using the system. Discuss treatment decisions with your HCP.

WARNING: Do not use the SmartGuard™ feature for people who require less than 8 units or more than 250 units of total daily insulin per day. A total daily dose of at least 8 units, but no more than 250 units, is required to operate in the SmartGuard™ feature.

WARNING: Do not use the MiniMed™ 780G system until appropriate training has been received from a healthcare professional. Training is essential to ensure the safe use of the MiniMed™ 780G system.

WARNING: Do not use SG values to make treatment decisions, including delivering a bolus, while the pump is in Manual Mode. When the SmartGuard™ feature is active and you are no longer in Manual Mode, the pump uses an SG value, when available, to calculate a bolus amount. However, if your symptoms do not match the SG value, use a blood glucose (BG) meter to confirm the SG value. Failure to confirm glucose levels when your symptoms do not match the SG value can result in the infusion of too much or too little insulin, which may cause hypoglycemia or hyperglycemia.

Pump therapy is not recommended for people whose vision or hearing does not allow for the recognition of pump signals, alerts, or alarms. The safety of the MiniMed™ 780G system has not been studied in pregnant women or in persons using other anti-hyperglycemic therapies that do not include insulin. For complete details of the system, including product and important safety information such as indications, contraindications, warnings and precautions associated with system and its components, please consult <https://www.medtronicdiabetes.com/important-safety-information#minimed-780g-instinct> and the appropriate user guide at <https://www.medtronicdiabetes.com/download-library>.

Important Safety Information for Extended Infusion Set: The Extended Infusion Set is indicated for up to 7 days of wear for the subcutaneous infusion of insulin from an infusion pump. It is NOT indicated for intravenous (IV) infusion or the infusion of blood or blood products. Inaccurate medication delivery, infection and/or site irritation may result from improper insertion and maintenance of the infusion site. Before insertion, clean the insertion site with isopropyl alcohol. Remove the needle guard before inserting the infusion set. If using this infusion set for the first time, do the first set-up in the presence of your healthcare professional. Do not leave air in the infusion set. Prime completely. Check frequently to make sure the soft cannula remains firmly in place as you may not feel pain if it pulls out. The soft cannula must always be completely inserted to receive the full amount of medication. If the infusion site becomes inflamed, replace the set, and use a new site until the first site has healed. Replace the infusion set if the tape becomes loose, or if the soft cannula becomes fully or partially dislodged from the skin. Regularly replace the infusion set as indicated in the instructions for use, or per the insulin labeling, whichever duration is shorter. For more details, see <https://www.medtronicdiabetes.com/important-safety-information>.

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