



**Loop**  
CamAPS | FX

# Clinical insights



## **mylife Loop – glucose management with Simplified Meal Announcement (SMA)<sup>1</sup>**



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## Take home messages

### **mylife Loop powered by mylife CamAPS FX**

- is an Automated Insulin Delivery (AID) system with clinical evidence that Simplified Meal Announcement (SMA) is non-inferior to exact Carbohydrate Counting (CC) for glucose management in youth and young adults with type 1 diabetes (T1D).<sup>1</sup>
- **gives freedom of choice for** adolescents and young adults with T1D using mylife CamAPS FX.<sup>1</sup>
- SMA offers an alternative to support optimal mealtime insulin administration for adolescents and young adults with T1D **by reducing the perceived burden of CC** and simplifying diabetes management.<sup>1</sup>



## Background and objective

- Carbohydrate counting is considered a cornerstone of mealtime insulin dosing for individuals with T1D.<sup>2,3</sup>
- However, research has shown that accurately counting carbohydrates is challenging for both, children and adults, with T1D.<sup>4,5</sup>
- Most commercial Hybrid Closed Loop (HCL) systems require the user to enter the grams of carbohydrate contained in a particular meal to facilitate prandial insulin delivery.<sup>3</sup>
- A more pragmatic meal management strategy with announcement of standard carbohydrate meal sizes may reduce the perceived burden of carbohydrate counting.<sup>1</sup>
- **The objective of the SMASH study was to evaluate the effectiveness of SMA compared to precise carbohydrate counting in managing post-meal glucose levels. This study focused on youth and young adults with T1D using mylife Loop. The researchers aimed to determine whether SMA could potentially simplify diabetes management while maintaining effective glycaemic management.**<sup>1</sup>



## Methods & participants

### SMASH:

- 46 participants across 2 University Hospitals in Switzerland were randomized in a crossover design in
  - Intervention group: mylife Loop (mylife CamAPS FX, mylife YpsoPump and Dexcom G6) with SMA
  - Comparator group: mylife Loop (mylife CamAPS FX, mylife YpsoPump and Dexcom G6) with exact CC
- Participants: age 12–20 years, T1D, MDI (n=35), SAP (n=4) or HCL therapy (n=7), HbA1c of 7.5 % ± 1 % (58.0±10.6 mmol/L/mol).
- Primary endpoint: percentage of time with glucose levels within the target range of 3.9–10.0 mmol/L (70–180 mg/dL).**

### The interventions:

- During the 3-month SMA period, participants announced their meals using individually pre-set categories, such as “snack”, “small”, “medium” or “large” meal sizes.
- During the 3-month CC period, participants calculated the exact carbohydrate content of their meals and announced it for insulin dosing.

### Procedure:

- During the CC period, participants were instructed to input the quantity of grams of carbohydrates (CHO) into the bolus calculator (lower line for CHO entry).
- A standard amount of CHO meal sizes was established for the SMA period based on a three-day record of CHO intake prior to the start of the study period. Participants quantified and documented the amount of CHO consumed using their usual CC method. The mean CHO intake per meal was rounded and categorized as a medium meal size. A snack was defined as 25 %, a small meal as 50 %, and a large meal as 150 % thereof.

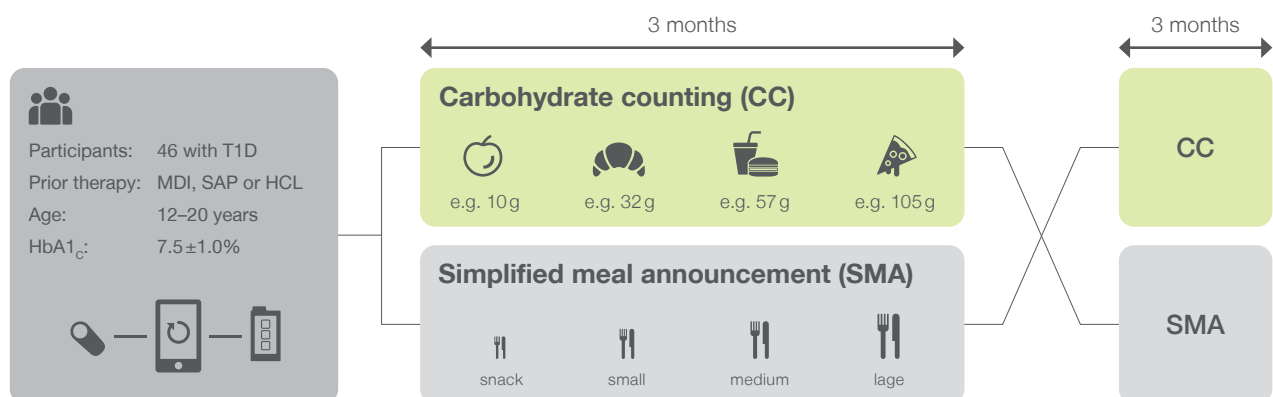
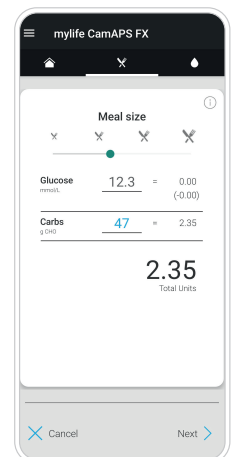


Fig. 1: Study design of the randomised crossover, non-inferiority trial.<sup>1</sup>



## Outcomes

### Primary endpoint

The primary endpoint assessment was a non-inferiority comparison between the percentage of Time in Range (TIR) during each 3-month study period for both, the SMA and CC.

The primary endpoint, defined as the proportion of time sensor glucose was in the target range between 3.9 mmol/L and 10.0 mmol/L (70 mg/dL and 180 mg/dL), was **70.7±13.0% with CC and 69.9±12.4% with SMA (p=0.48)**. The mean difference between the two study groups was -0.6 percentage points (95% CI -2.4, 1.1), indicating that **SMA demonstrated non-inferiority** as shown in figure 2.

These findings are further supported by comparable results for time spent in low (<3.9 mmol/L (<70 mg/dL)) and high (>10.0 mmol/L (>180 mg/dL)) glucose ranges between SMA and CC (figure 2).

**These results demonstrate that SMA is an effective alternative to CC, reducing the complexity of diabetes management.<sup>1</sup>**

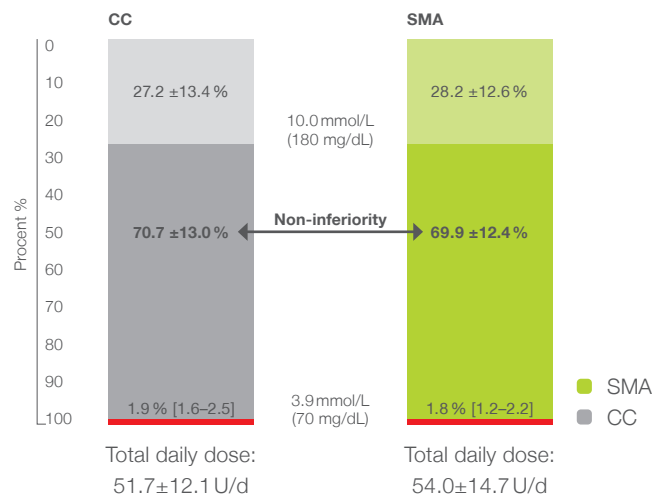


Fig. 2: The non-inferiority of TIR with SMA and CC indicates that SMA is an effective alternative to exact CC.

### Secondary endpoints

In addition to the primary outcome, the study also assessed several secondary outcomes, including HbA1c levels, CGM-based glucometrics, insulin doses and patient-reported outcomes.

- **HbA1c:** a comparison of HbA1c levels following the two three-month periods demonstrated a **similar change in HbA1c** in both interventions: SMA:  $-0.35\% \pm 0.94\%$  vs. CC:  $-0.31\% \pm 0.97\%$ , ( $p=0.59$ ).
- **Bolus frequency and doses**, both for meals and corrections, did not significantly differ between SMA and CC periods.
- **Total Daily Dose (TDD)** of insulin was significantly higher during SMA than during CC ( $54.0 \pm 14.7$  U/day vs  $51.7 \pm 12.1$  U/day, mean difference 2.4 U/day [95 % CI 0.1, 4.7]). This was attributable to higher automated insulin delivery ( $36.4 \pm 13.0$  U/day vs  $33.6 \pm 10.9$  U/day,  $p = 0.0041$ ), resulting in a 4.5 % higher insulin dose with SMA compared to CC.

The learning of the algorithm considers meal bolus information to adapt post-meal insulin delivery, particularly when meals are not adequately covered by user-initiated bolus administration. Consequently, in the event of the quantity of carbohydrates consumed in a meal being below the expected amount, the algorithm will provide the supplementary insulin that is required.

- **User experience:** as reflected in the INSPIRE (Insulin delivery Systems: Perceptions, Ideas, Reflections and Expectations) scores, there was no significant difference in user experience between the study periods (SMA  $66.4 \pm 14.3$ , CC  $67.1 \pm 16.4$ ,  $p = 0.74$ ), yielding no evidence, that user satisfaction increased with SMA.

### Conclusion

The SMASH study concluded that **SMA is a viable alternative to precise CC** for managing meals in youth and young adults with type 1 diabetes. It **simplifies meal management, reduces the cognitive burden** associated with diabetes care, and **maintains effective glycaemic management**. This approach has the potential to improve the quality of life for individuals managing type 1 diabetes with mylife Loop and confirms performance of mylife CamAPS FX, which continuously modulates insulin and therefore adapts post-meal insulin delivery, particularly when meals are not adequately covered by user-initiated bolus. However, SMA requires the pre-set meal-size to be appropriately individualised for the user to have this outcome.


**mylife Loop powered by mylife CamAPS FX with Simplified Meal Announcement (SMA) reduces the burden of carbohydrate counting.**

Glucose levels are measured by continuous glucose monitoring systems, either Dexcom G6 or Freestyle Libre 3 / Libre 3 Plus sensors.

Insulin is delivered with the mylife YpsoPump insulin pump.



mylife CamAPS FX adjusts insulin delivery every 8 to 12 minutes, based on the current and the predicted glucose levels.

 Visit our website for detailed information about mylife Loop:  
[www.mylife-diabetescare.com/loop](http://www.mylife-diabetescare.com/loop)

**Abbr:** **CC:** Carbohydrate Counting; **CHO:** Carbohydrate; **HCL:** Hybrid closed loop; **MDI:** Multiple Daily Injections; **SAP:** Sensor-Augmented Pump therapy; **SMA:** Simplified Meal Announcement; **TDD:** Total Daily Dose; **T1D:** Type 1 Diabetes

- 1 Laesser CI, et al. Simplified meal announcement study (SMASH) using hybrid closed-loop insulin delivery in youth and young adults with type 1 diabetes: a randomised controlled two-centre crossover trial. *Diabetologia*. 2024
- 2 Haidar A, et al. Reducing the need for carbohydrate counting in type 1 diabetes using closed-loop automated insulin delivery (artificial pancreas) and empagliflozin: A randomized, controlled, non-inferiority, crossover pilot trial. *Diabetes Obes Metab*. 2021 Jun;23(6):1272-1281.
- 3 Petrovski G, et al. Simplified Meal Announcement Versus Precise Carbohydrate Counting in Adolescents With Type 1 Diabetes Using the MiniMed 780G Advanced Hybrid Closed Loop System: A Randomized Controlled Trial Comparing Glucose Control. *Diabetes Care*. 2023 Mar 1;46(3):544-550.
- 4 Brazeau AS, et al. Carbohydrate counting accuracy and blood glucose variability in adults with type 1 diabetes. *Diabetes Res Clin Pract*. 2013 Jan;99(1):19-23.
- 5 Gurnani M, et al. One potato, two potato,... assessing carbohydrate counting accuracy in adolescents with type 1 diabetes. *Pediatr Diabetes*. 2018 Nov;19(7):1302-1308.

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 For safety information on mentioned products, see Instructions for Use or [www.mylife-diabetescare.com/safety](http://www.mylife-diabetescare.com/safety)



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